

Quality Standards for Auditory Implant Services

Version 1.0 January 2024

Introduction

Background

Following the successful implementation of the Adult Rehabilitation, Paediatric, Vestibular and Adult Tinnitus Quality Standards in Wales, it was felt that the Auditory Implant Services in Wales would benefit from a similar approach in order to maintain an equitable, high-quality service across Wales.

Work began developing the Auditory Implant Quality Standards in early 2021. This involved joint working with representatives leading in Auditory Implant Service delivery across Wales. The aim was to develop a comparable self-assessment and external audit process for this specialised area of Audiology. It was also agreed that the existing Adult Rehabilitation Quality Standards and/or Paediatric Quality Standards are pre-requisites for compliance with the Auditory Implant Quality Standards. And so, all Audiology departments hosting an Auditory Implant Service in Wales are expected to be fully compliant with the existing Adult Rehabilitation Quality Standards and/or Paediatric Quality Standards.

Health Boards are expected to support their own specialist Audiology staff in participating in external audit of other Health Boards. A lay member (third sector representative) and/or patient representative will also be present at external audits.

Development of Quality Standards for Auditory Implant Services in Wales

A Working Group was set up which included senior Audiology and ENT clinicians and managers from across Wales with significant experience in Cochlear Implants (CI), Bone Conduction Hearing Implants (BCHI) and Middle Ear Implants (MEI) along with third sector representatives from National Deaf Children's Society (NDCS), Royal National Institute for Deaf people (RNID) and Cochlear Implanted Children's Support Group (CICS). A small survey conducted by the National Deaf Children's Society Cymru to gather thoughts of parents of service users on what makes a good implantable device service also fed into the development of these standards. The working group's main objective was to jointly develop Quality Key Performance Indicators in the form of Quality Standards for Auditory Implant Services offering BCHI, CI and/or MEI in Wales.

Consultation

The draft version of these standards has undergone a two-stage consultation, firstly with Wales Heads of NHS Audiology Services, then more widely with individual local ENT Consultants and Audiovestibular Physicians, Clinical Psychologists, Speech and Language Therapists, Paediatricians and representatives from the British Cochlear Implant Group (BCIG), National Cochlear Implant Users Association (NCIUA), National Deaf Children's Society (NDCS), Royal National Institute for the Deaf (RNID), Cochlear Implanted Children's Support Group (CICS), British Academy of Audiology (BAA) and Commissioners. Feedback from the consultation was used to further develop these Quality Standards.

Approach and Context to Describing Service Quality

The Standards cover the following areas:

Quality Standards for Auditory Implant Services in Wales
Std 1 Accessing the Service
Std 2 Information Provision and Communication
Std 3 Assessment
Std 4 Surgery
Std 5 Post-operative Management
Std 6 Clinical Skills and Expertise
Std 7 Outcomes & Service Improvement

Auditory Implant Quality Standards

Format

The Quality Standards comprise 7 *Standard Statements* that explain the level of performance that needs to be achieved. These *Standard Statements* are supported by an evidence base that provides the *Rationale* for each Standard. The *Standard Statements* are expanded into several *Criteria* which specify what must be achieved for the standard to be met. The *Standard Statements* are listed below. The evidence base, the references that support them and the detailed *Criteria* are all detailed within the *Assessment and Audit Tool* that accompanies this document.

Some standards include Key Performance Indicators (KPIs) within the Criteria. These are highlighted in bold within the standards. These KPIs are intended to identify some key areas for monitoring performance and service quality that can guide decision-making within a service.

Standard 1 – Accessing the Service

All patients and their families/significant others/carers who require access to an Auditory Implant Service for assessment for Bone Conduction Hearing Implant (BCHI), Cochlear Implant (CI) or Middle Ear Implant (MEI) can:

- Access an Auditory Implant Service that addresses their needs in a timely manner
- Have access to the Welsh Auditory Implant Service closest to their home

Service demand and referral data are accurately recorded, monitored, reviewed, analysed and reported against available indicators and used to guide service planning. Access times are benchmarked against other comparable Auditory Implantable Services.

Patients living in all areas of Wales have equitable access to Auditory Implant Services.

All Auditory Implant patients have access to effective, ongoing lifetime maintenance and support.

Standard 2 - Information provision and Communication

There must be a timely and relevant two-way exchange of comprehensive information to address the individual needs of hearing-impaired/deaf/Deaf patients and their significant other(s), in formats that accommodate their communicative abilities e.g., British Sign Language, Braille, Welsh language, easy read. Patients and families should be given appropriate opportunity to discuss and ask questions throughout.

The use of technology should be offered to enable Auditory Implant team members to communicate effectively with patients and to ensure that the information is given in a manner that the patient understands.

Standard 3 –Assessment

All patients receive a full audiological and medical assessment which is carried out safely, to recognised national standards, where available, and appropriate to their needs and abilities, which includes:

- A comprehensive and relevant medical, developmental, communication and audiological history (to include tinnitus, vestibular and ENT history)
- For children, assessment of general development, functional listening and speech, language and communication
- Understanding and evaluation of the effect of their hearing loss on daily life and activity limitations
- Evaluation of social and environmental communication and listening needs
- Understanding and exploration of motivation, attitude, expectation and behaviours as a result of their hearing loss and surrounding the concept of receiving a BCI/CI/MEI
- For children, parental /carers' expectations and understanding of the potential impact of their child's hearing loss on their development
- Testing, including adaptations for disabilities and contraindications where necessary
- Assessment of rehabilitation needs and goals

In addition, paediatric patients will have access to the following additional services/support:

- Speech and Language Therapist (SLT)
- Qualified Teacher of the Deaf (QToD)
- Paediatrician

All patients will have access to the following additional services/support if required:

- ENT / Audiovestibular medicine (AVM)
- Balance team
- Tinnitus team
- Diagnostic Audiology
- Anaesthetics

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- Psychology
- Social services
- Support from existing implant users (volunteers)
- Genetics

All equipment used during assessment must be well maintained and calibrated as necessary.

Findings are sent to the referrer, GP and other relevant professionals (e.g., Health Visitor) in a timely and professional manner.

Standard 4 –Surgery

BCHI, CI and MEI surgery should be overseen by an appropriately experienced Consultant ENT surgeon with completion of recognised training.

All surgery should be performed safely in operating theatres to recognised national standards, where available.

All patients should be assessed medically and have risks of general/local anaesthesia discussed in preparation for surgery.

All patients/parents/carers should be well-informed of procedures before, during and after surgery.

Standard 5 – Post-Operative Management

Within the first year following surgery all patients should be offered structured appointments comprising of switch-on and a series of formal reviews. After the first year, reviews should be patient-led with the option of a remote or face-to-face appointment. Annual contact with all patients should be attempted. Children will need to be seen more frequently for face-to-face appointments based on assessment of their needs.

All patients should have an individually developed management plan (IMP) for the management of their goals. This plan:

- Is based on information gathered at the assessment and post-switch on phase
- Is determined in conjunction with the patient/parents/carers and/or their significant other(s)
- Is updated on an ongoing basis
- Is accessible to the clinical team
- Is available to the patient in accessible language and format
- Its use, outcome and effectiveness are evaluated and recorded

All patients should be offered ongoing maintenance of their processor as and when required and an upgrade of their processor every 5 years if this provides clinical benefit.

Standard 6 - Clinical skills and expertise

Each Auditory Implant service provides, within a governed multi-disciplinary team (MDT) approach, the clinical competencies necessary to safely and effectively support the assessments and interventions they undertake.

Each service has processes in place to keep up to date with and employ key innovations relevant to Auditory Implant assessment and rehabilitation along with an established peer review process.

Standard 7 – Outcomes & Service Improvement

Auditory Implant outcomes are monitored, evaluated and recorded.

Outcomes and effectiveness of the service are evaluated and recorded to identify trends and patterns which may inform service development and planning.

Quality of service delivery is measured and improved using Patient Reported Experience Measures (PREMs). These should be collected on at least an annual basis and should include elements on access, communication and information. Outcomes of these PREMs should be made available and shared where possible.

Each service has processes in place to regularly consult with patients and stakeholders. Any feedback received should be acted on in a timely manner.

The Individual Management Plan

An Individual Management Plan (IMP) is central to the Quality Standards for Adult Hearing Rehabilitation Services and Paediatric Quality Standards and is an idea firmly rooted in good practice. The concept of an IMP has been adopted by the Auditory Implant Teams in Wales as it also fits in with our patient's pathways. It involves a minute of the conversation between Audiologist and/or Rehabilitationist and patient/parents/carers about what the patient feels, wants or expects; what the team can offer; and how the team and patient agree to proceed.

There is no specified template for the IMP. It is assumed that services will keep detailed notes of the conversations in their patient records. An IMP is not a case history form or a record of assessment results although the patient's case history and hearing status will certainly help to inform the IMP and are therefore likely to be summarised within it. An Auditory Implant IMP's main aim is to record the goals and needs of the patient as they progress as an Auditory Implant user helping guide the Audiologist and/or Rehabilitationist to support the patient in an individualised manner.

Through conversation and an exchange of information at their appointments, the Audiologist and/or Rehabilitationist and the patient will explore what can and cannot be done and the agreed needs and actions for the patient will be reviewed and updated during their visits.

Rehabilitation staff working with children use session plans and strategies which have adopted the Person-Centred approach central to the Additional Learning Needs legislation. These documents can be shared with patients, parents/carers and local professionals in a format appropriate to the collaborative nature of the work with children.

The Evidence Base

"Evidence-based medicine is the integration of best research evidence with clinical expertise and patient values," (Sackett et al., 2000 p. 1).

A comprehensive review of the current evidence base has been undertaken. Wherever possible the working group prioritised evidence in National documents where available, then considered evidence in large scale reviews, followed by evidence in peer reviewed, published research.

There are also several overarching documents that have informed the development of the Quality Standards, and these are listed below.

- Welsh Assembly Government, 2003. Fundamentals of Care. Wales: Welsh Assembly Government
- Welsh Assembly Government 2006. National Service Framework for Older People in Wales. Wales: Welsh Assembly Government
- The Equality Act 2010
- Welsh Assembly Government, 2010. Doing Well, Doing Better. Standards for Health Services in Wales. Wales: Welsh Assembly Government
- Welsh Government, 2011. Together For Health. A 5-Year Vision For The NHS in Wales. Wales: Welsh Government
- Welsh Assembly Government, 2011. Fairer Health Outcomes For All. Reducing Inequities in Health Strategic Action Plan. Wales: Welsh Assembly Government.
- Aylward, M., Phillips, C. and Howson, H. 2013. Simply Prudent Healthcare – achieving better care and value for money in Wales – discussion paper. Wales: Bevan Commission, Simply Prudent Healthcare
- Welsh Government, 2017. Framework of Action for Wales, 2017-2020. Integrated framework of care and support for people who are D/deaf or living with hearing loss
- Welsh Government, 2021. A Healthier Wales: our plan for Health and Social Care. Wales: Welsh Government
- Welsh Government, 2021. National Clinical Framework: A Learning Health and Care System. Wales: Welsh Government

Principles and Key Features of the External Audit Process Against the Standards

The objective of the audit process is to externally verify self-assessment scores (and evidence). The objective is not to perform an appraisal of service management and/or make extensive recommendations for improvement.

The audit process should be robust, relevant, efficient, fair and consistent.

A full self-assessment will have been completed 6 weeks prior the external visit and evidential materials compiled for reference at the time of the visit of the external auditors.

Visits will be conducted jointly by an external audit team; comprising an independent auditor, and a lead auditor, who must be a senior clinician from another service.

All Health Boards which provide Auditory Implant services will be visited every three years by external auditors. Each Health Board will submit oneself assessment score, which will incorporate all the services they provide, including those which are provided to other Health Boards through a service level agreement.

The visit of the external auditors will be completed over a day, with additional time required for travel. Only the base centre would be visited rather than peripheral sites.

Externally assessed scores must be presented to the Chief Executives and Heads of Audiology for each respective service, prior to being made available to ASSAG and put in the public domain (e.g., on the WSAC website).

A coordinator will be appointed by ASSAG to administer the scheme, collate results and report to ASSAG following each audit.

An appeals mechanism will exist where external scoring or the audit process can be challenged.

Assessment and Audit Tool

Quality Standards for Auditory Implant Services in Wales

Please note:

All Audiology departments hosting Auditory Implant Services in Wales are expected to comply with ARQS and/or PQS as a pre-requisite of these Quality Standards.

Evidence of compliance – this list contains examples that you may wish to include as evidence. You may have different forms of evidence to support your self-assessment score.

Key Performance Indicators (KPIs) are highlighted in bold

Standard 1 - Accessing the Service			
Standard Statement	Rationale and References	Criteria	Evidence of Compliance
1a. All patients and their families/significant other and/or carers thought to benefit from an auditory implant can access Auditory Implant Services for assessment of eligibility in a timely manner within clearly defined pathways.	Effective allocation of health resources is reliant upon accurate information on the balance between demand for services and available resources. We must ensure access for all patients, in accordance with equality laws and across geographical areas. (1,2)	1a.1 Referrals for BCHI, CI and/or MEI assessment are seen within 6 weeks following receipt of referral, unless the patient requests otherwise. 1a.2 Clearly defined pathways exist for new referrals including fast-track cases (if applicable).	Written referral pathways, linked to referral criteria, for all referral routes. Pathways should include classification of appointments (fast-track/routine). Service SOPs with version numbers to be included, and documents to be updated at least every 3 years, or sooner should changes occur.

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1b. Auditory Implant Services support Implant Champions based in Audiology departments to improve awareness and accessibility of auditory implantable devices.	Auditory implant champions improve engagement and communication between referral centres and auditory implant centres. Champions can improve awareness and increase quality of referrals from Audiology departments. Champion scheme is currently being evaluated by BCIG.	1b.1 Auditory implant teams encourage and support the appointment of implant champions within each referring audiology department. 1b.2 Auditory Implant teams should engage with Implant Champions to provide support and updates when required.	Written/electronic document for referrers detailing referral pathways and criteria. Record of named champions and evidence of active engagement.
1c. Service demand and referral data are accurately monitored, reviewed and reported against available indicators and used to guide service planning.	The number of appropriate and inappropriate referrals to the specialist medical route informs the effectiveness/clarity of the criteria and compliance of referrers to those criteria. Improvements can then be made to ensure that patients are not incorrectly referred to certain services and that patients meeting implantation criteria are referred in a timely way (3). Effective allocation of health resources is reliant upon accurate information on the balance between demand for services and available resources. It is important that waiting times for all stages of the patient pathway from referral	1c.1 Key data are collected, reviewed, analysed, used in annual service review and analysed and discussed with Health Boards on an annual basis; this should include as a minimum: • Age at referral • Total number of referrals • Total number of implants • Number of referrals by referring centre/area • Referral to treatment times • Reasons for exiting the assessment pathway • Patient postcodes • Implantation rates based on population	Record of key data and analysis of data. Audit of waiting times, against target. Data on the number of referrals within/outside criteria, broken down e.g., by referral centre. Data collected on patient home location in order to review accessibility to services based on socio-economic status (via Welsh Index of Multiple Deprivation).

	through to treatment are collected and monitored in an effective manner. The use of IT systems to compute information such as demographic data and waiting times will inform allocation of services and help prevent an overload of patients accessing the same services and resources being strained (3,4,5,6) Effective allocation of resources relies upon information on actual demand and potentially/projected demand for specific services (3,4,5,6)	1c.2 Evidence of action taken if there is evidence of under referral, inappropriate or poor quality referrals from referring Audiology services.	Record of data collected on quality of incoming referrals. AWA day data collection and discussion
1d. Patients should be able to access an Auditory Implant Service at each phase of patient management: • Assessment • Pre-operative • Post-operative management	Young people need a clear transition route from child to adult services (7,8) Information should be shared with BCI, CI and/or MEI manufacturers to inform of device cumulative survival rate data. (1)	1d.1 Services should allow flexibility of appointment times/dates/location when feasible based on patient's needs. 1d.2 The number of patients transferring into or out of the service at each stage is monitored. 1d.3 Defined pathways are in place for transition from paediatric to adult Auditory Implant service with clear information and support available to patients. 1d.4 Auditory implant services should provide information on deceased patients to manufacturers.	Record of data on the number of patients transferring in or out of the service. Transition/transfer in SOPs. Record of informing manufacturers of deceased patients. Record of data on the number of patients within each stage of the pathway.

Standard 2 - Information Provision and Communication			
Standard Statement	Rationale and References	Criteria	Evidence of Compliance
2a. There must be a timely and relevant two-way exchange of information to address the needs of the patients and their significant other(s), families and/or carers in formats that accommodate their communicative abilities.	Good, timely communication before, during and after appointments benefits patients and their significant others/families, through reduction in anxieties/concerns and encouraging appropriate uptake of further care (9,10,11,12,13,14,15,16,17,18,19) Written information that is clear, up to date and in a format that is accessible to the individual facilitates understanding of the service (ARQS 9,16,20,21,22). To avoid discrimination, services should meet the specific communication and information needs of hearing-impaired/deaf/Deaf patients and their significant other(s)/family accessing the service (19,23,24,25). Technology should be used to enable Auditory Implant staff to	2a.1 Written information available in plain language Welsh and English is provided in an appropriate format for all new patients prior to their appointment. This includes information on: how to contact the implant centre through a variety of ways including phone, email, letter and/or SMS • location and parking arrangements • expected length of time of appointment • what to expect from the initial appointment? Patients should also be alerted to inform the department should interpretation be required for the appointment. 2a.2 Communication needs are recorded and actioned and BSL and spoken language interpreters should be available when requested.	Examples of written patient information leaflets and letters, available in Welsh and English. Referral forms to include communication support requirements. Auditbase alerts indicating communication preferences. Plain English/Welsh (or similar) on all information and letters. Examples of video information and/or translated information sheets. Evidence of access to translation and interpretation services. Shared access inbox for patients to contact service and access to departmental mobile phone.

	communicate effectively with patients (where appropriate and approved by patient) and to ensure that the information is given in a manner that the patient understands. This may include video calls, remote interpretation services and online communication/instructions (16, 26,27). Information should be available online for those interested in BCHI/CI/MEI to access at their own leisure. (1, 28, 29)	2a.3 Appropriate written information is available in plain Welsh and English language during assessment phase on: • BCHI/CI/MEI • surgical procedure • risks of surgery • expectations • treatment process • relevant other organisations Alternative formats and translations are available on request. 2a.4 All patients receive a verbal debrief from the clinician regarding test results, whether in or out of criteria and next steps with an opportunity to discuss concerns. Where patients are children and young people, appointments should involve discussion with both the family and the child/young person themselves so that, where they have capacity, children and young people have a clear understanding of their care and are able to be actively involved in planning their care.	
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2b. Technology should be used to enable Audiology staff to communicate effectively with patients and to ensure that the information is given in a manner that the patient understands.		2b.1 The use of technology is offered as a way of communicating with patients when preferred over face-to-face contact. 2b.2 Information should be available online about BCHI, CI and/or MEI, the treatment process and any other relevant organisations.	Evidence of appropriate use of departmental website. Video consultation software available and evidence of offering video consultation appointments. Evidence of communicating with patients/families/carers over email when requested.
2c. Data protection guidelines are followed when sharing information about patients.	Local Information Governance policies should be adhered to. Data protection legislation should be always adhered to – Data Protection Act (2018) and Common Law Duty of Confidentiality. (1)	2c.1 Appropriate data governance arrangements e.g., Data Protection Impact Assessment (DPIA) are to be in place where data is held and shared outside of the Health Board. 2c.2 Consent should be obtained by patients/parent or guardian before information is shared either internally or externally (except for safeguarding purposes).	Evidence of DPIAs Evidence of consent for data sharing.

Standard 3 – Assessment			
Standard Statement	Rationale and References	Criteria	Evidence of Compliance
3a. All patients receive an individually tailored assessment which is carried out to recognised national standards, where available, to inform a decision in patients' best interest. This may include: • A full audiological and medical history • Radiological assessment • Measurement of hearing impairment • Evaluation of current hearing aids / trial of hearing aids • Assessment of activity limitations and impact on QoL related to hearing impairment • Evaluation of attitudes, expectation, motivation • Paediatrics – evaluation of communication skills at home and school, educational support and	Accurate and complete assessment is required to inform decisions and discussions regarding support and management options. (30,31,32,33). A full medical history is required to: • inform the surgeons and medical team of any possible contraindications to surgery • to develop an IMP Understanding the patient's attitudes, expectations and motivation of an implant will enable appropriate pre-operative counselling. (1,2,28,29,34)	3a.1 Services have facilities to perform the full range of tests required within assessment and follow national guidance when applicable. 3a.2 Clinicians adapt or omit tests where appropriate due to contraindications or patient needs. 3a.3 All patients receive relevant assessment tailored to their age and needs which may include input from: • Local Audiology department • QToD • SLT • Paediatrician • Education professionals • Tinnitus team • Balance team • Diagnostic Audiology • Psychology • ENT/AVM • Anaesthetics • Genetics	Patient journals. SOPs Case studies demonstrating adaption of assessment based on individual needs. Case audit. Evidence of collaborative working with professionals noted in 3a.3. Documented clinical pathways. Patient journals and reports written by relevant professionals.

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environment, and peer relationships			
3b. Patients undergoing assessment should be given the opportunity to meet other existing implant users.	Sharing experiences with other users during assessment is extremely valuable. Paediatric patients should be offered family contacts to share experiences with (35). (28,29)	3b.1 All patients undergoing assessment for implantation and considering proceeding with surgery should be offered to meet or connect with other implant users/families to share experiences.	SOP Case studies. Patient journals. Record of user groups/user meetings.
3c. Candidacy criteria is based on most up to date evidence.	(2,28,29,34)	3c.1 All patients who proceed through assessment to consent are eligible for the specified auditory implant based on their audiological thresholds and otological status. 3c.2 Where implantation is not bilateral: - all patients have appropriate tests to decide on the appropriate ear for implantation e.g., vHIT in CI patients - discussion on ear choice is documented.	Patient journals. Ongoing departmental audits and data collection. Case studies.

		3c.3 Consideration is given to device choice when possible, in discussion with the patient/family/carer.	
3d. Outcomes of assessment is shared appropriately.	(1,28)	3d.1 Summary reports with clear recommendations in plain language are sent to the patient/families/carers within 10 working days of completion of assessment. 3d.2 A letter is sent to GP/referrer from MDT clinic stating outcome of assessment in a timely manner. 3d.3 When implantation is not recommended, where appropriate an appointment is offered to discuss this decision with the appropriate professionals, and this is followed by a written report. Emotional support or onward referral for emotional support is available if required. Where the patient is a child or young person the outcome is discussed in an appropriate way for the child or young person to understand. 3d.4 Pathways exist for onward referral when required e.g., to ABI centres, from BCHI to CI teams.	Examples of onward referral letters. Examples of reports to referrers. Patient journals/case studies. Auditbase records on report completion.

Standard 4 – Surgery			
Standard Statement	Rationale	Criteria	Evidence of Compliance
4a. Auditory implant surgery is offered to all medically and audiotologically suitable patients in a timely manner.	All patients who are medically fit and are eligible for an auditory implant should be discussed in an MDT for suitability prior to be offered the procedure in a timely manner. Cochlear implant surgery under local anaesthesia is feasible (36). Early cochlear implantation gives best outcome in post-meningitic cases (37). (1,34)	4a.1 Patients should be considered for the most appropriate auditory implantable device following full Audiological assessment, exploration of hearing needs and MDT review. 4a.2 Discussion and decision to offer BCI/CI/MEI surgery should take place at the Auditory Implant MDT. Procedure must be agreed to be in the patient's best interest to proceed. 4a.3 All patients should have appropriate pre-operative medical assessment including all preparation for surgery e.g., pneumococcal vaccination prior to CI surgery. 4a.4 Consideration should be given for type of anaesthesia used - general or local.	Patient journals. Ongoing audits. Case audits. MDT clinic records. SOPs. AWA data collection and discussion

		4a.5 All patients are offered a surgery date within 26 weeks of their referral date or 36 weeks if complex case, except for early referred babies where an optimal surgery date may be around 12 months. Surgical prioritisation should be given for: • post-meningitis patients (CI) • explantation/reimplantation (all devices) • infants under 5 years old For children where there are delays in implantation beyond 26 weeks, the reason for this delay should be monitored and shared.	
4b. Auditory implant surgery should be performed by appropriately qualified and fully trained ENT surgeons following manufacturers guidelines where applicable.	Auditory implant services should have access to a minimum of two experienced ear surgeons with completion of recognised appropriate training for a specific implantable device. Surgical activity, of the order of 10 per year per surgeon, must be sufficient to maintain high levels of skills and experience (BCIG Quality	4b.1 Services should have at least two Consultant ENT surgeons with otology specialist experience within MDT with at least one surgeon present for all MDT discussions. 4b.2 Auditory implant surgeons should be undertaking: • Cochlear implants surgery - 10 surgeries per year per surgeon in order to maintain	Evidence of registration, training and/or training. Case audits. Ongoing audits. Patient journals. Records of surgeries. Surgical SOPs.

	Standards: Cochlear Implant Services for Children and Adults) Surgical outcomes should be audited regularly to ensure complication rates are within acceptable range (38). Two-stage surgeries should be considered for children when required (skull thickness <3mm) (2,28,29)	high levels of skills and experience • BCHI & MEI – up to date training in order to maintain surgical competency and number of surgeries per year should be monitored 4b.3 Surgical SOPs and manufacturer guidelines should be followed for each surgical procedure with minimally invasive techniques being used where possible. 4b.4 Surgery should be overseen by a consultant surgeon with completion of recognised training for a specific implantable device. 4b.5 Services should have access to facilities that enable them to deal with any immediate emergency post-operative complications. 4b.6 All post-operative complications are recorded and monitored.	AWA reports. Surgical database.
4c. Patients should be given appropriate written information pre- and post-operatively.	Patient should be given information in plain language on: • Risk of surgery	4c.1 Patients should have access to, and the opportunity to discuss the following appropriate information during the consent process:	Evidence of written patient information with version dates and evidence of amendments if applicable.

	• What to expect before, during and after surgery • Guidance on day of surgery arrangements • Post-operative guidance (1,28) Patients and families and/or carers should have a liaison nurse who gives the advice and guidance on abutment care and wound care.	• surgical procedure • benefits, alternatives and risk of surgery/surgical intervention • arrangements on day of surgery • management of hearing and communication between surgery and device activation 4c.2 Patients should have access to, and the opportunity to discuss the following post-operative information and advice: • wound care • pain management • emergency contacts upon discharge following surgery	Evidence of discussion with patients in journal/IMP. Evidence of available information online. SOPs
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Standard 5 – Post-operative management			
Standard Statement	Rationale	Criteria	Evidence of Compliance
5a. Patients are offered initial activation of their device in a timely manner.	Sufficient time should be allowed for the surgical area to heal post-operatively. (1,28,29)	5a.1 Patients should be offered timely appointments for device activation in line with current medical guidance.	Case studies. SOPs.
5b. Patients are offered appropriate programming and rehabilitation schedules post-device activation.	Hearing rehabilitation is an important part of managing a hearing loss and has a significant effect on quality of life (39) Rehabilitation may be self-directed, done by friends and family, via online resources or by direct contact with rehabilitation staff (depending on patients' preference). For children, rehabilitation strategies will form part of their local support plans and be developed in collaboration with rehabilitation staff. Direct contact with rehabilitation staff will be in homes, schools, or	5b.1 Clearly defined post-operative pathways are in place to ensure sufficient access to fitting and review appointments. Pathways should be: • Appropriate • Flexible • Patient-led A minimum number of formal reviews within the first 12 months of use should be set within pathways. For adult patients these should include formal audiological, speech perception and Quality of Life (QoL) measures as appropriate. In addition, for children these could also include developmental milestones and development of	SOPs. Patient journals and review reports. Ongoing audits. Patient information. Evidence of documentation of liaison with education services. Surgical database.

	other educational settings as well as clinic. Bespoke training of local support professionals is required to appropriately support newly implanted children. (1,28)	speech, language and communication skills. 5b.2 Rehabilitation should be offered on an individualised basis and should include the use of various tools, resources and methodologies including online support based on individual needs. For Paediatrics there should be evidence of co-working and sharing information between rehabilitation and educational colleagues/local services. 5b.3 A written report/IMP should be shared with the patient/families and appropriate professionals following appointments where planned/key actions are agreed. 5b.4 Patients should be reviewed by an ENT surgeon or for BCHI patients an appropriately trained ENT aural care nurse at least once post-operatively. 5b.5 Annual review should be patient-led and offered as either a remote appointment or face-to-face	
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		appointment taking into account the patient's preference.	
5c. All patients should have an IMP for the management of their needs. This plan: • Is based on information gathered at the assessment and immediate post-switch on phase • Is determined in conjunction with the patient and/or their significant other • Is updated and reviewed on an ongoing basis • Is accessible to the clinical team and patient • Includes recommended interventions to best meet the needs of the individual patient • Is available to the patient	Patient involvement in their own care improves outcomes. An effective IMP will detail specific actions associated with agreed goals that consider a listener's social, communication and listening needs, in addition to their related activity limitations (10). Each child should have an IMP that is reviewed and developed with the child and/or parents and shared with parents and key professionals (35).	5c.1 Patients who have received an auditory implantable device have a jointly agreed IMP that is shared with the patient/parents/carers. 5c.2 Review schedules are appropriate to the individual patient and set-up based on the patients' needs and as part of their IMP. 5c.3 Patients/families and/or carers should be clearly signposted to relevant support services and third sector organisations if required. 5c.4 All patients/families and/or carers should be informed of the Magnetic Resonance Imaging (MRI) compatibility of their internal device and should be encouraged to contact their auditory implant service should they require an MRI.	Evidence of IMP. Patient journals. Case studies. SOPs. Evidence of signposting/onward referral and patient information regarding third sector organisations. Evidence of recording of MRI scans for CI users.
5d. All patients' external device and associated equipment should be maintained.	(1,28,29)	5d.1 All patients' external devices are registered with the appropriate manufacturers post-implantation.	SOPs e.g., upgrades, repairs, accessory issue. Written patient information.

		5d.2 All patients should be given and have access to essential consumables either: • directly • by local audiology departments (batteries only) • contracted manufacturers support schemes 5d.3 All patients, families and/or carers are instructed, supported and given clear information on use and maintenance of their external devices and equipment, including the use of any accessories e.g., waterproof covers. 5d.4 All patients, families and/or carers are instructed and given clear information on safety guidance. 5d.5 All patients should have a documented discussion and information provided regarding provision of assistive technology and listening devices. Where patients have access to assistive devices provided by the auditory implant service they should be supported to be confident in using these devices.	Evidence of issuing assistive listening devices where appropriate. Repair audits. Record of upgrades. Lost processor policy/records.
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		5d.6 Patients who have a faulty processor should have access to another suitable working device within 2 working days. Patients, families and/or carers should be clear on how to access repair services. 5d.7 Patients who have a lost or damaged beyond repair processor should have access to another suitable working device within 2 working days. Patients, families and/or carers should be made aware early in the pathway that there may be a charge as set out in service policies. 5d.8 Upgrade of processors should be offered where clinically appropriate every 5 years.	
5e. Any suspected cases of implant device failures should be addressed as a priority.	Auditory implant internal devices are highly reliable. However, device failures can occur which require proactive management without delay. Device failures should be reported to the relevant UK statutory body – Medicines and	5e.1 All patients who present with: • suspected CI failure should be treated as a clinical emergency • suspected BCI/MEI failure should be treated as clinically urgent.	SOP. Case audits. Ongoing service audits/record keeping.

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	Healthcare Products Regulatory Agency as soon as possible. (1,28,29)	5e.2 All implant failures should be reported to the MHRA and to the manufacturers at the earliest possible opportunity. 5e.3 Should revision surgery be required this should be offered and arranged as soon as is clinically possible with priority given to unilateral implant users. This information should be shared with relevant professionals.	Patient/surgical database including recording of explantation and device failures. MHRA reporting record. Record of revision surgeries.
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Standard 6 – Clinical Skills and Expertise			
Standard Statement	Rationale	Criteria	Evidence of Compliance
6a. Auditory implant services should have an established MDT setup that involves a variety of professionals that may include (but not limited to): • Auditory implant co-ordinator • Auditory implant clinical staff – clinical scientists/audiologists • ENT surgeons/AVM Physicians • ENT nurses • SLT • Psychologists • Paediatricians • QToD	Auditory implant services should be delivered by a MDT of specialist professionals with expertise in otology, clinical science, clinical physiology and rehabilitation. Teams should have knowledge and skills to work with children and adults with a range of complex needs, additional to their deafness. MDT working impacts assessment, management plans and adherence to clinical guidelines (40) (28,29,34)	6a.1 Auditory implantable services conduct regular MDT meetings/discussions with various appropriate professionals present. 6a.2 Clinicians should have the relevant training available to work with patients with a range of complex needs, additional to their deafness to allow them to adapt their pathway based on the patients' needs.	MDT minutes/record of MDT discussions. SOP Evidence of additional training available e.g., dementia, learning difficulties, mental capacity act for patients lacking capacity to consent. Case studies demonstrating how clinical pathways are adapted based on patient's needs.
6b. Each Audiology service demonstrates that they have the clinical competencies necessary to support the assessments and interventions they undertake and keep up to date with key developments and innovations.	Auditory implant departments have a duty of care and must ensure that assessments and interventions are delivered by appropriately trained, qualified and registered clinicians.	6b.1 Peer review is carried out for all members of staff leading appointments within the auditory implant service, at least every 3 years, for relevant appointment types and procedures. A local peer review procedure is followed.	Evidence of staff peer review and outcomes/reports. Staff peer review policy/SOP. Evidence of staff registration status.

	Regulatory Bodies' 'Standards of Proficiency' statements detail requirements for registered practitioners to remain registered. These are produced for the safe and effective practice of the professions they regulate and are deemed to be the minimum standards which are necessary to protect members of the public (41,42,43,44). Registration bodies and some employers require demonstration of regular CPD activity (45,46,47,48,49,50) Auditory implants are a constantly changing field and clinical competency must, therefore, be maintained through continuing professional development. Peer review provides a useful approach to help ensure clinical competencies are maintained (48,49). Newly appointed staff should undergo a process of mentoring under supervision of senior colleagues.	6b.2 All staff performing auditory implant appointments are registered with a relevant statutory or voluntary body e.g., HCPC, AHCS, RCCP, EWC, BATOD, RCSLT. Delegation of duties to lower banded unregistered, trained staff may be appropriate for certain appointments e.g., repairs. 6b.3 All staff must be appropriately trained to undertake the duties of their role. 6b.4 All clinical staff undertaking auditory implant assessment or rehabilitation participate in CPD activity relevant to their job role. 6b.5 The Auditory Implant service keeps up to date with: • any national developments related to auditory implant services and shares this information with patients, families and/or carers accordingly • any relevant training and developments released by manufacturers	Staff training status and records. Evidence of staff qualifications. Evidence of delegation processes. Evidence of CPD records and training records. Record of meetings/training events. Email updates.
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	(1,28)		
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Standard 7 – Outcomes and Service Improvement			
Standard Statement	Rationale	Criteria	Evidence of Compliance
7a. Patient outcomes are monitored through a variety of measures.	Clinical benefit is evaluated through performance assessment and questionnaires. These should be obtained before implantation and at regular intervals post-implantation. Services may benefit from participating in UK-wide sharing of data to inform clinical practice and service development in the UK e.g., for CI sharing data with BCIG when requested. Recording data on an auditory implant registry has many benefits including informing national guidance and policy, improving quality and safety and improving the evidence-base (51). (1,28)	7a.1 Individual outcomes are evaluated and recorded for all patients at appropriate stages within the patient pathway by use of appropriate outcomes measures: • ADULTS: - hearing - communication - quality of life • PAEDIATRICS: - hearing - speech, language and communication development - education - quality of life 7a.2 Services should contribute data to national audits and/or national registry, and action improvements where shortfalls are identified.	Ongoing departmental audits. Patient journals. Record of PROMS. SOPs. Data reports. AWA audit report / BCIG audit report / Registry record. For children and young people - contribution to Person Centred Plan (PCP)/Individual Developmental Plan (IDP) review and formal reports to all professionals involved at 6-, 12-, 24- and 36-months post implant. Documented evidence of improvements to service delivery

7b. The outcome and effectiveness of the Individual Management Plan is evaluated and recorded.		7b.1 Individual outcomes are evaluated and recorded for all patients.	Outcomes audit/ongoing audit. Case studies.
7c. Quality of service delivery is measured and improved using Patient Reported Experience Measures (PREMs). These should be collected on at least an annual basis and should include elements on access, communication and information. These should be used to plan and implement service improvements.	Measurement of qualitative and quantitative data helps to inform ongoing service improvement (52,53,54,55,56,57) Patient experience is an important aspect of service quality. (1)	7c.1 The Auditory Implant service collects qualitative and quantitative data relating to service performance and service user experience on an annual basis. This should cover all aspects of the pathway including assessment, surgical and post-op management. 7c.2 Patients, parents and/or carers have the opportunity to complete anonymous surveys to determine satisfaction with different elements of the service received. Children/Young people are given the opportunity to give feedback in appropriate format. 7c.3 The results of PROMS and PREM surveys are used to identify areas for improvement and any feedback received is acted upon. Results of these surveys and planned actions in response to the outcome of these surveys are displayed within departments and shared as relevant, e.g., with CHSWGs.	Service review framework/SOP that outlines 'what, when where and how' this data will be collected and reported. Results from service user satisfaction questionnaires/PROMs/PREMs. Evidence that results are used to identify areas for improvement. Evidence of working with CHSWGs (paediatric services only).

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7d. Auditory implant services communicate regularly with referrers, service users and stakeholders.	Audiology services that seek, consider and respond to the views of users will be more likely to meet the needs of their patients (58,59,60,61) Auditory implant services should engage and provide referral centres with regular updates and opportunity for collaborative service improvement and development. (1)	7d.1 Auditory implant services are in regular contact with referral centres and all relevant professionals and deal with queries as they arise e.g., implant champions, educational services. 7d.2 Auditory implant services engage with service users and stakeholders before making substantial changes/developments to their service.	Evidence of liaising and dealing with queries from referral sites and/or CI champions/relevant professionals/educational services. Evidence of departmental PPI/service user engagement framework or plans.
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Glossary:

ARQS = Adult Rehabilitation Quality Standards

AVM = Audiovestibular Medicine

AWA = All Wales Audit

BCHI = Bone Conduction Hearing Implant

CHSWG = Children's Hearing Services Working Group

CI = Cochlear Implant

CPD = Continuous Professional Development

DPIA = Data Protection Impact Assessment

ENT = Ear, Nose and Throat

HA = Hearing Aid

IDP = Individual Development Plan

IMP = Individual Management Plan

MDT = Multi-disciplinary team

MEI = Middle Ear Implant

MHRA = Medicines and Healthcare Products Regulatory Agency

MRI = Magnetic Resonance Imaging

PCP = Person Centred Plan

PPI = Patient and Public Involvement

PREMs = Patient Reported Experience Measures

PROMs = Patient Reported Outcome Measures

PQS = Paediatric Quality Standards

QoL = Quality of Life

QToD = Qualified Teacher of the Deaf

SLT = Speech and Language Therapy

SOPs = Standard Operational Procedure

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