1. Population Needs

1.1 National/local context and evidence base

There are approximately 697,500 people older than 16 years with severe to profound deafness in England, with 575,500 of these of retirement age. In adults, age-related damage to the function of hair cells in the cochlea, presbycusis, is the most common cause of deafness in England. Hearing loss in adults may also be caused by excessive exposure to noise, or by ototoxic drugs, metabolic disorders, infections, injury or genetic factors.

Approximately 370 children in England are born with permanent severe to profound deafness each year. About 1 in every 1000 children is severely or profoundly deaf at 3 years old. This rises to 2 in every 1000 children aged 9 to 16 years. About half the incidence of childhood deafness is attributed to genetic causes, although approximately 90% of deaf children come from families with no direct experience of deafness. Causes of severe to profound hearing loss in children also include conditions such as meningitis and viral infection of the inner ear (for example, rubella or measles), as well as premature birth and congenital infections.

As prevalence of deafness is strongly associated with older age and due to the aging population profile in England, the numbers of those with severe to profound deafness can be
predicted to increase. There are more females than males with hearing loss although this is associated with females living longer rather than gender differences in causes of deafness. Some minority ethnic groups may have higher rates of hearing loss due to increased genetic risk associated with consanguinity and increased risk of childhood infections. Approximately 40% of children who are deaf and 45% of people younger than 60 years who are deaf have additional difficulties, such as other physical or sensory disabilities.

Cochlear Implantation is a process that involves the surgical implantation of an electrode array in to the cochlea to provide direct electrical stimulation of the auditory nerve. A microphone, transmitter coil and sound processor unit worn on the side of the head transmits to the internal receiver-stimulator package. The resulting electrical stimulation of the auditory nerve provides auditory sensation but does not restore normal hearing. A cochlear implant may be suitable for patients who have a high frequency functional severe to profound sensorineural hearing loss bilaterally and who derive limited benefit from conventional hearing aids. Binaural hearing, either through bilateral implantation or bimodal listening is recommended for this patient group.

Refer to NICE TAG 166 2009 Guidance for cochlear implants for severe to profoundly deaf patients at http://www.nice.org.uk. This document details the criteria under which cochlear implants will be routinely funded.

2. Outcomes

2.1 NHS Outcomes Framework Domains & Indicators

<table>
<thead>
<tr>
<th>Domain</th>
<th>Preventing people from dying prematurely</th>
<th>Enhancing quality of life for people with long-term conditions</th>
<th>Helping people to recover from episodes of ill-health or following injury</th>
<th>Ensuring people have a positive experience of care</th>
<th>Treating and caring for people in safe environment and protecting them from avoidable harm</th>
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</table>

Core service standards can be found in Section 4 and also Appendix 1.
The following key patient outcomes shall be achieved by Providers of the Service:

- >90% adults and >90% children using their cochlear implant consistently and reliably
- >80% of all patients to have thresholds of 40 dB HL or better in implanted ears
- Improvement in developmentally age appropriate speech perception scores &/ or Quality of Life
- Service to present evidence of improvement in auditory and/or speech outcomes monitored in children
- >90% of patients reporting themselves to be satisfied or very satisfied with the service & their implant 12 months after surgery
- All audiological equipment must be calibrated to British Standards at least annually, and a system of daily checking in place.

3. Scope

3.1 Aims and objectives of service

The aim of a cochlear implant service is to improve the hearing and quality of life for those with high frequency functional severe to profound permanent deafness who do not gain adequate benefit from conventional well-fitted hearing aids and to promote understanding and the use of spoken language in children.

The service will deliver the aim by:

- Providing equitable access for all eligible children and adults
- Providing a service which is clinically and cost effective
- Providing appropriate long term support and aftercare.

Additional considerations for paediatric caseload

Aims for paediatric rehabilitation

- To promote the normal development of auditory awareness and comprehension
- To provide a remediation service in these cases – this could be through direct input or an advisory service

3.2 Service description/care pathway

Service Delivery

A cochlear implant team may function independently or as part of a wider service including paediatric, adult and teens cochlear implant services.
Resources
The multidisciplinary team should comprise a core team as detailed in the BCIG quality standards for both children and adults as detailed at: http://www.bcig.org.uk/downloads/pdfs/BCIG%20Adult%20Quality%20Standards%202010.pdf

These to include:
- Cochlear Implant Co-ordinator/ Head of Service Role
- Clinical Scientists (Audiology/Clinical Physics)
- Clinical physiologists (Audiology), and Rehabilitationists / Hearing Therapists
- Speech & Language Therapists
- Consultant Otologists

Education and Training
All team members must be suitably qualified and registered with appropriate professional bodies and comply with the relevant requirements. All members should maintain continued professional development (CPD) and appraisal. They will also be members of their relevant cochlear implant professional groups (e.g. ICAG, ICTOD) All will have training in deaf awareness. Clinical team members will attend regular training in developments within the field of cochlear implantation. Attendance at relevant courses, conferences and meetings at national and international levels is desirable.

Newly appointed members of the team who are less experienced must undergo an appropriate programme of induction and training with supervision provided by relevant experienced members of a cochlea implant team. All team personnel must maintain a programme of continued professional development to ensure ongoing competency.

Care Pathway
All patients will undergo comprehensive assessment by a specialist multi-disciplinary team to assess suitability for cochlear implantation.

Assessment will include all or some of the following:
- Audiological assessments
  - Otoscopy, age-appropriate behavioural hearing assessment, objective hearing assessments, hearing aid evaluation, aided speech perception testing, balance function testing as required, adhering to relevant and up to date test protocols
- Patient / family / carer understanding and expectations of implantation and informed consent
- Medical assessments
  - Clinical history, physical examination, fitness for surgery, suitability of cochlear for implantation, radiological evaluation via CT &/or MRI imaging
- Rehabilitative team assessments
  - Speech and language skills, functional listening, quality of life, ability to
participate in rehabilitation programme, developmental level of child, availability of support & liaison with local services.

The service will provide support to all patients, including those with complex and special needs, and ensure access to further appropriate services and care for these patients as necessary. When appropriate, suitable communication support must be provided to permit equal access for deaf patients e.g. BSL interpreters, speech to text.

As part of the assessment process, patients who may be candidates for implantation and their families / carers as appropriate, will receive information about voluntary services and support groups including opportunity to have contact with deaf patients of a similar age (and their families for paediatric patients) who are users of cochlear implants, either face to face or via alternative media. Patients will be offered written information to help them to make informed decisions about their healthcare, at appropriate points within the assessment.

If the outcome of the assessment demonstrates that the patient would not benefit from a cochlear implant, the report to the referring agent will include:

- Reasons why a cochlear implant is considered to be unsuitable.
- Recommendations for future management, and referral for other equipment and /or services if appropriate.

Adults will demonstrate that they have realistic expectations of cochlear implantation, e.g. by using a measurement tool such as an expectations questionnaire.

The Cochlear implant device offered will

- Have a proven track record for safety
- Have CE approval
- Conform to the recommendations of the Medical and Health Care Products Regulatory Agency
- Comply with terms and conditions of the purchasing body
- Have high quality clinical and technical support available from the manufacturer
- Meet national purchasing requirements

The in-patient episode will include the following:

- The operation - completed by an experienced, specialist ENT Consultant Surgeon. Implantation must be carried out by appropriately qualified surgeons who have an adequate caseload to maintain surgical skills and optimise outcomes.
- Intra-operative testing completed when clinically necessary
- Surgical facilities must afford appropriate NHS standards of safety, accessibility, cleanliness, privacy and dignity and also take into account communication needs of deaf patients. The facilities should also comply with BCIG Quality Standards

**Discharge, continuing care and rehabilitation**

Prior to discharge the patient will receive:
• Written information regarding care of the wound/ear and pain management post operatively
• Written guidelines on what to do should medical /surgical problems arise.
• Advice regarding health and safety with a cochlear implant
• Written BCIG safety guidelines

The service will ensure that the more intensive rehabilitation needs of the patient will be appropriately addressed.

Rehabilitation requirements include:
• Medical check following implantation of surgical site and device placement and functioning
• Initial activation and programming of speech processor
• On-going sound processor programming and assessment dependent on individual need
• After the first year following implant surgery, the patient will be offered regular audiological review, typically annually. Flexibility for additional appointments will be available if required to adequately meet the needs of the patient
• Recognised & validated developmental age appropriate audiological and speech perception measures will be performed on at least two occasions in the first year.
• Sound awareness training in adults and development of listening skills in children.
• Communication skills training in adults and development in children.
• Listening and language skills development training and / or support on an individual patient needs basis.
• Training provided at the centre and as outreach where appropriate. Advice to patient (and carers if appropriate) on care and use of the implant
• Advice to other organisations e.g. trouble shooting advice for local staff (for children)
• On-going support and maintenance – including a comprehensive spares and repairs service.
• Medical – access to the implant medical / surgical team as required
• Upgrade or provision of new sound processors on average at 5 yearly intervals, where available, in order to ensure patient access to up to date technology to maximise their hearing performance and subsequently outcome from the intervention.

Patients and or carers will be trained by the service to carry out simple trouble-shooting and maintenance such as visual inspection of external parts and subjective listening checks (where possible). For more complex maintenance needs, the cochlear implant service will provide advice via telephone, fax, e-mail, text etc. and make arrangements whereby external implant parts can be brought or posted to the service during opening hours. The service will aim to resolve repair and replacement issues within 2 working days. Spares/ replacements of external equipment will be provided as required. Batteries will be available to implant users either from the cochlear implant programme or from a local audiology department by prior agreement.
Patients will be advised they have access to urgent medical support as per the standard access for acute ENT emergency care in the Provider unit.

The service will have appropriate policies which cover, as a minimum:
- Device failure
- Lost processor/s
- FM policy and Assistive Devices
- Upgrade of speech processor/s
- Transfer of care pathway from/to another service

The service will provide re-implantation if required. Costs outside those included in the manufacturer’s warranty are the responsibility of the commissioner. Any device failures must be reported to the MHRA Adverse Incidents section. If device failure is suspected the patient must be offered an appointment within 7 working days to check the external and internal components of the implant device.

Essential repairs, consumables and spare parts will be provided free of charge to users. Users may be asked to pay for non essential items e.g. decorative covers, holiday loaners and for repair or replacement of parts or devices if damage, loss or failure is determined to be due to inappropriate care, with appropriate provision for appeal.

If, following a multi-disciplinary team assessment, it is determined that patients are not suitable for a cochlear implant, the service will ensure that:
- The patient and/or the family have the opportunity to discuss the outcome of the assessment.
- The referrer, the local audiology department, other relevant professionals and the patient’s GP are notified that the patient has been discharged from the Service.

Records of measurement of all programmes installed in the software, and of all tests performed by the multi-disciplinary team, must be kept. Progress with the cochlear implant will be monitored through at least three assessments in the first year and then again at routine reviews which should be offered at a minimum annually after the switch on. These tests will include the patient’s ability to hear sounds and speech, as well as assessment of quality of life.

All records and measurements will be available on request and provided, with consent to other parties, who may have a legitimate reason for using them, e.g. education, health services etc. The service will engage in audit and monitoring of service outcomes with data shared with commissioners and appropriate external organisations. Guidance on a minimum dataset is provided at the end of this specification in section 4.

**Audit, Governance, Quality Improvement**

The following are over-arching principles that are to be applied to each provider delivering a
cochlear implantation service:

- Consideration must be given to the needs of a deaf population in all aspects of the design of the service.
- There must be clearly defined clinical and managerial accountability within the service.
- All work processes are to be protocol-led and clearly defined. Any deviation from these protocols will be clearly documented and investigated with regular reviews led by the commissioners with support from each provider and updated where appropriate.

Unless alternatively specified in this document, providers are expected to meet the following quality standards for age-appropriate services:


Both are available as free downloads from www.bcig.org.uk

Where elements of the cochlear implant service are sub-contracted to another provider, there must be clear and formal accountability processes and structures in place to ensure continuity of clinical care that is safe and effective. All subcontracting agreements have to be agreed in advance with the commissioners. The contract with the provider and the subcontractor will mirror the standard NHS contract (or successor documents) with the provider and the commissioner. Sub-contractors will be expected to provide services of the same level and quality of service as the centre.

Please refer to http://www.mapofmedicine.com for the Cochlear Implant pathway

When treating children, the service will additionally follow the standards and criteria outlined in the Specification for Children’s Services (attached as Annex 1 to this Specification)

3.3 Population covered

The service outlined in this specification is for patients ordinarily resident in England*; or otherwise the commissioning responsibility of the NHS in England (as defined in Who Pays?: Establishing the responsible commissioner and other Department of Health guidance relating to patients entitled to NHS care or exempt from charges).

* Note: for the purposes of commissioning health services, the EXCLUDES patients who, whilst resident in England, are registered with a GP Practice in Wales, but INCLUDES patients resident in Wales who are registered with a GP Practice in England.

3.4 Any acceptance and exclusion criteria and thresholds

Cochlear implantation services include multi-disciplinary assessment, surgical
implantation and rehabilitation (including maintenance of the implant). This applies to provision in adults and children.

Cochlear implants are hearing devices that require surgical implantation to address either a specific type of hearing loss or to address hearing loss that cannot be corrected with conventional hearing aids.

All patients are initially referred for general hearing assessment and see an audiologist and an ENT surgeon. The assessment process for cochlear implants is generally led by audiology.

The NHS Commissioning Board (NHS CB) commissions cochlear implantation services. This includes the multi-disciplinary assessment, surgical implantation and rehabilitation (including maintenance of the implant). Clinical Commissioning Groups (CCGs) commission the initial general hearing assessment for patients who go on to have specialist assessment for cochlear implants.

The service will accept referrals from:
- GP
- NHS or private Audiology Service
- Ear, Nose and Throat (ENT) Service
- Paediatrician

Written referrals will be made to the cochlear implantation service providing evidence of:
- Unaided hearing level in both ears at frequencies of 2kHz and 4 kHz (for babies and young children this may not be possible to assess fully prior to referral)
- Where possible, evidence of a hearing aid trial of at least 6 weeks or a reason as to why this is contraindicated or inappropriate.

When considering the assessment of adequacy of acoustic hearing aids, the multidisciplinary team must be mindful of the need to ensure equality of access. Tests will take into account a person’s disabilities (such as physical and cognitive impairments), or linguistic or other communication difficulties, and may need to be adapted. If it is not possible to administer tests in a language in which a person is sufficiently fluent for the tests to be appropriate, other methods of assessment will be considered. Providers will be expected to monitor uptake of services to assess equity of access. Uptake of cochlear implantation may be expected to mirror prevalence severe to profound deafness with some variation according to age, ethnicity and presence of other disability.

NICE TAG 166 (Guidance for cochlear implants for severe to profoundly deaf patients) details the criteria under which cochlear implants will be routinely funded.

### 3.5 Interdependencies with other services/providers
Co-located services - to be provided on the same site and to be immediately available 24/7
There are no services that are required to be co-located

Interdependent services – to be available 24/7, not necessarily in site
There are no interdependent services that are required 24/7

Interdependent services – available during daytime hours
The service has interdependencies with the following services:

- Primary Care
- NHS Audiology Service
- NHS Newborn Hearing Screening Programme
- Appropriate rehabilitative services which may include Speech & Language Therapy, Educational Services including Teacher of the Deaf or other specialist teaching services, Social Services including Social worker for the deaf, Occupational therapy, Physiotherapy, and Psychology.

4. Applicable Service Standards

4.1 Applicable national standards
Services will be provided in specialist cochlear implant centres. As the rehabilitation required to support successful use of cochlear implants can be intense, these services are expected to be provided by the nearest cochlear implant centre or on an outreach/shared care basis where appropriate.

Cochlear Implant Services must have access to appropriately calibrated and up-to-date equipment and facilities to enable all appropriate assessments to be undertaken. Audiological testing will be performed in appropriately sound treated rooms where possible such that the ambient noise levels are compliant with the BBS EN ISO 8253-1:1998 standard, Acoustics:- Audiometric test Methods – part 1.

Facilities will afford appropriate NHS standards of safety, accessibility, cleanliness, privacy and dignity and also take into account communication needs of deaf patients and requirements for specific assessments such as sound-proofing. The design and layout will take into account the needs of families and young children within their client group. Services, facilities and accommodation must comply with current British standards and the Equality Act 2010. All facilities must comply with Health and Safety Executive regulations.
Core Standards

| The service will be provided by a centre that has a team that is capable of assessing all patients with profound hearing loss and rehabilitating them appropriately with conventional hearing aids |
| There must be an appropriately qualified core MDT consisting as a minimum of audiological scientist, audiologist, speech or hearing therapist and surgeon. In the children’s programmes there must also be age appropriate educational and speech professionals |
| All patients will be assessed by the core MDT |
| The service will only use cochlear implant devices that have CE approval |
| The service will have in place policies covering device failure and loss of processors |
| The service must have a minimum of two specialist ENT surgeons with demonstrable, on going, up to date experience of cochlear implantation |
| Each patient will have a documented care plan which details their rehabilitation needs |

5. Applicable quality requirements and CQUIN goals

5.1 Applicable quality requirements (See Schedule 4 Parts A-D)

These are in the process of being developed and will be inserted once agreed.

5.2 Applicable CQUIN goals (See Schedule 4 Part E)

These are in the process of being developed and will be inserted once agreed.

6. Location of Provider Premises

The Provider’s Premises are located at:

7. Individual Service User Placement

Appendix One
Quality standards specific to the service using the following template:

<table>
<thead>
<tr>
<th>Quality Requirement</th>
<th>Threshold</th>
<th>Method of Measurement</th>
<th>Consequence of breach</th>
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<tbody>
<tr>
<td><strong>Domain 1: Preventing people dying prematurely</strong></td>
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<tr>
<td>Usage reported by patients 12 months after surgery</td>
<td>&gt;90% adults and &gt;90% children using their cochlear implant consistently and reliably</td>
<td>Annual audit</td>
<td>As per Standard NHS Contract, General Conditions Clause 8 and 9 (GC9) Remedial Action Plan</td>
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<tr>
<td>Use of auditory stimuli - Sound field implant aided thresholds assessed 12 months after implant surgery</td>
<td>&gt;80% of all patients to have thresholds of 40 dB HL or better in implanted ears</td>
<td>Annual audit</td>
<td>As per Standard NHS Contract, General Conditions Clause 8 and 9 (GC9) Remedial Action Plan</td>
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<tr>
<td>Improvement in developmentally age appropriate speech perception scores &amp;/ or QoL.</td>
<td>Improvement in previously reported score</td>
<td>Annual audit</td>
<td>As per Standard NHS Contract, General Conditions Clause 8 and 9 (GC9) Remedial Action Plan</td>
</tr>
<tr>
<td>Service to present evidence of auditory and/or speech outcomes monitored in children.</td>
<td>Improvements to be seen</td>
<td>Annual audit</td>
<td>As per Standard NHS Contract, General Conditions Clause 8 and 9 (GC9) Remedial Action Plan</td>
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<tr>
<td>All implanted patients to be offered at least one review appointment annually</td>
<td>100%</td>
<td>Annual audit</td>
<td>As per Standard NHS Contract, General Conditions Clause 8 and 9 (GC9) Remedial Action Plan</td>
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<tr>
<td>All audiological equipment must be calibrated to British</td>
<td>100%</td>
<td>Annual audit</td>
<td>As per Standard NHS Contract, General Conditions Clause 8 and 9</td>
</tr>
<tr>
<td>Quality Requirement</td>
<td>Threshold</td>
<td>Method of Measurement</td>
<td>Consequence of breach</td>
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<td>Standards at least annually, and a system of daily checking in place.</td>
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<td>(GC9) Remedial Action Plan Remedial Action Plan</td>
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**Domain 3: Helping people to recover from episodes of ill-health or following injury**

| Appropriate acceptance of referrals though written acknowledgement of referral within 5 working days | 100% | Annual audit | As per Standard NHS Contract, General Conditions Clause 8 and 9 (GC9) Remedial Action Plan |
| Successful Surgery - Post-operative surgical infection rate requiring explantation | Surgeons to comply with professional standards of the Royal College of Surgeons | Annual audit | As per Standard NHS Contract, General Conditions Clause 8 and 9 (GC9) Remedial Action Plan |

**Domain 4: Ensuring that people have a positive experience of care**

<p>| Waiting times - Receipt of referral letter to first offered appointment for accepted referrals | &gt;100% routine referrals within 6 weeks | Annual audit | As per Standard NHS Contract, General Conditions Clause 8 and 9 (GC9) Remedial Action Plan |
| Waiting times - Receipt of referral letter to first offered appointment for definitive treatment | &gt;80% within 18 weeks | Annual audit | As per Standard NHS Contract, General Conditions Clause 8 and 9 (GC9) Remedial Action Plan |
| Replacement of failed sound processors | &gt;80% within 2 working days of notification | Annual audit | As per Standard NHS Contract, General Conditions Clause 8 and 9 (GC9) Remedial Action Plan |
| Successful surgery - Failed devices reported to the MHRA | 100% | Annual audit | As per Standard NHS Contract, General Conditions Clause 8 and 9 (GC9) Remedial Action Plan |</p>
<table>
<thead>
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<th>Quality Requirement</th>
<th>Threshold</th>
<th>Method of Measurement</th>
<th>Consequence of breach</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality of life (adults and teenagers only)</td>
<td>Service to present evidence of improvement &amp; outcomes monitored</td>
<td>Annual audit</td>
<td>As per Standard NHS Contract, General Conditions Clause 8 and 9 (GC9) Remedial Action Plan</td>
</tr>
</tbody>
</table>

**Domain 5: Treating and caring for people in a safe environment and protecting them from avoidable harm**

| Percentage of patients / parents reporting themselves to be satisfied or very satisfied with the service & their implant 12 months after surgery | >90% of patients reporting themselves to be satisfied with their implant | Annual audit | As per Standard NHS Contract, General Conditions Clause 8 and 9 (GC9) Remedial Action Plan |
ANNEX 1 TO SERVICE SPECIFICATION:

PROVISION OF SERVICES TO CHILDREN

Scope
Aims and objectives of service

This specification annex applies to all children’s services and outlines generic standards and outcomes that would be fundamental to all services.

The generic aspects of care:
The Care of Children in Hospital (HSC 1998/238) requires that:
- Children are admitted to hospital only if the care they require cannot be as well provided at home, in a day clinic or on a day basis in hospital.
- Children requiring admission to hospital are provided with a high standard of medical, nursing and therapeutic care to facilitate speedy recovery and minimize complications and mortality.
- Families with children have easy access to hospital facilities for children without needing to travel significantly further than to other similar amenities.
- Children are discharged from hospital as soon as socially and clinically appropriate and full support provided for subsequent home or day care.
- Good child health care is shared with parents/carers and they are closely involved in the care of their children at all times unless, exceptionally, this is not in the best interest of the child; Accommodation is provided for them to remain with their children overnight if they so wish.

Service description/care pathway

All paediatric specialised services have a component of primary, secondary, tertiary and even quaternary elements.

The efficient and effective delivery of services requires children to receive their care as close to home as possible dependent on the phase of their disease.

Services should therefore be organised and delivered through “integrated pathways of care” (National Service Framework for children, young people and maternity services (Department of Health & Department for Education and Skills, London 2004)

Interdependencies with other

All services will comply with Commissioning Safe and Sustainable Specialised Paediatric Services: A Framework of Critical Inter-Dependencies – Department of Health.

Imaging

All services will be supported by a 3 tier imaging network (‘Delivering quality imaging services for children’ Department of Health, 13732 March 2010). Within the network:
• It will be clearly defined which imaging test or interventional procedure can be performed and reported at each site.
• Robust procedures will be in place for image transfer for review by a specialist radiologist, these will be supported by appropriate contractual and information governance arrangements
• Robust arrangements will be in place for patient transfer if more complex imaging or intervention is required
• Common standards, protocols and governance procedures will exist throughout the network.
• All radiologists, and radiographers will have appropriate training, supervision and access to continuing professional development (CPD)
• All equipment will be optimised for paediatric use and use specific paediatric software.

Specialist Paediatric Anaesthesia

Wherever and whenever children undergo anaesthesia and surgery, their particular needs must be recognised and they should be managed in separate facilities, and looked after by staff with appropriate experience and training.\(^1\) All UK anaesthetists undergo training which provides them with the competencies to care for older babies and children with relatively straightforward surgical conditions and without major co-morbidity. However those working in specialist centres must have undergone additional (specialist) training\(^2\) and should maintain the competencies so acquired\(^3\) *. These competencies include the care of very young/premature babies, the care of babies and children undergoing complex surgery and/or those with major/complex co-morbidity (including those already requiring intensive care supports).

As well as providing an essential co-dependent service for surgery, specialist anaesthesia and sedation services may be required to facilitate radiological procedures and interventions (for example MRI scans and percutaneous nephrostomy) and medical interventions (for example joint injection and intrathecal chemotherapy), and for assistance with vascular access in babies and children with complex needs such as intravenous feeding.

Specialist acute pain services for babies and children are organised within existing departments of paediatric anaesthesia and include the provision of agreed (hospital wide) guidance for acute pain, the safe administration of complex analgesia regimes including epidural analgesia, and the daily input of specialist anaesthetists and acute pain nurses with expertise in paediatrics.

*The Safe and Sustainable reviews of paediatric cardiac and neuro- sciences in England have noted the need for additional training and maintenance of competencies by specialist anaesthetists in both fields of practice.
References

1. Guidelines for the Provision of Anaesthetic Services (GPAS) Paediatric anaesthetic services. Royal College of Anaesthetists (RCoA) 2010 [www.rcoa.ac.uk]
2. Certificate of Completion of Training (CCT) in Anaesthesia 2010
3. CPD matrix level 3

Specialised Child and Adolescent Mental Health Services (CAMHS)

The age profile of children and young people admitted to specialised CAMHS day/in-patient settings is different to the age profile for paediatric units in that it is predominantly adolescents who are admitted to specialised CAMHS in-patient settings, including over-16s. The average length of stay is longer for admissions to mental health units. Children and young people in specialised CAMHS day/in-patient settings generally participate in a structured programme of education and therapeutic activities during their admission.

Taking account of the differences in patient profiles the principles and standards set out in this specification apply with modifications to the recommendations regarding the following:

- Facilities and environment – essential Quality Network for In-patient CAMHS (QNIC) standards should apply [http://www.rcpsych.ac.uk/quality/quality.accreditationaudit/qnic1.aspx]
- Staffing profiles and training - essential QNIC standards should apply.
- The child/ young person’s family are allowed to visit at any time of day taking account of the child / young persons need to participate in therapeutic activities and education as well as any safeguarding concerns
- Children and young people are offered appropriate education from the point of admission.
- Parents/carers are involved in the child/young person’s care except where this is not in the best interests of the child / young person and in the case of young people who have the capacity to make their own decisions is subject to their consent.
- Parents/carers who wish to stay overnight are provided with accessible accommodation unless there are safeguarding concerns or this is not in the best interests of the child/ young person.

Applicable national standards e.g. NICE, Royal College

Children and young people must receive care, treatment and support by staff registered by the Nursing and Midwifery Council on the parts of their register that permit a nurse to work with children (Outcome 14h Essential Standards of Quality and Safety, Care Quality Commission, London 2010)

- There must be at least two Registered Children’s Nurses (RCNs) on duty 24 hours a day in all hospital children’s departments and wards.
• There must be a Registered Children’s Nurse available 24 hours a day to advise on the nursing of children in other departments (this post is included in the staff establishment of 2RCNs in total).

Accommodation, facilities and staffing must be appropriate to the needs of children and separate from those provided for adults. All facilities for children and young people must comply with the Hospital Build Notes HBN 23 Hospital Accommodation for Children and Young People NHS Estates, The Stationary Office 2004.

All staff who work with children and young people must be appropriately trained to provide care, treatment and support for children, including Children’s Workforce Development Council Induction standards (Outcome 14b Essential Standards of Quality and Safety, Care Quality Commission, London 2010).

Each hospital which admits inpatients must have appropriate medical cover at all times taking account of guidance from relevant expert or professional bodies (National Minimum Standards for Providers of Independent Healthcare, Department of Health, London 2002). "Facing the Future” Standards, Royal College of Paediatrics and Child Health.

Staff must carry out sufficient levels of activity to maintain their competence in caring for children and young people, including in relation to specific anaesthetic and surgical procedures for children, taking account of guidance from relevant expert or professional bodies (Outcome 14g Essential Standards of Quality and Safety, Care Quality Commission, London 2010).

Providers must have systems in place to gain and review consent from people who use services, and act on them (Outcome 2a Essential Standards of Quality and Safety, Care Quality Commission, London 2010). These must include specific arrangements for seeking valid consent from children while respecting their human rights and confidentiality and ensure that where the person using the service lacks capacity, best interest meetings are held with people who know and understand the person using the service. Staff should be able to show that they know how to take appropriate consent from children, young people and those with learning disabilities (Outcome 2b) (Seeking Consent: working with children Department of Health, London 2001).

Children and young people must only receive a service from a provider who takes steps to prevent abuse and does not tolerate any abusive practice should it occur (Outcome 7 Essential Standards of Quality and Safety, Care Quality Commission, London 2010 defines the standards and evidence required from providers in this regard). Providers minimise the risk and likelihood of abuse occurring by:

• Ensuring that staff and people who use services understand the aspects of the safeguarding processes that are relevant to them.
• Ensuring that staff understand the signs of abuse and raise this with the right person when those signs are noticed.
• Ensuring that people who use services are aware of how to raise concerns of abuse.
• Having effective means to monitor and review incidents, concerns and complaints that have the potential to become an abuse or safeguarding concern.
• Having effective means of receiving and acting upon feedback from people who use services and any other person.
• Taking action immediately to ensure that any abuse identified is stopped and suspected abuse is addressed by:

  ➢ having clear procedures followed in practice, monitored and reviewed that take account of relevant legislation and guidance for the management of alleged abuse
  ➢ separating the alleged abuser from the person who uses services and others who may be at risk or managing the risk by removing the opportunity for abuse to occur, where this is within the control of the provider
  ➢ reporting the alleged abuse to the appropriate authority
  ➢ reviewing the person's plan of care to ensure that they are properly supported following the alleged abuse incident.

• Using information from safeguarding concerns to identify non-compliance, or any risk of non-compliance, with the regulations and to decide what will be done to return to compliance.
• Working collaboratively with other services, teams, individuals and agencies in relation to all safeguarding matters and has safeguarding policies that link with local authority policies.
• Participates in local safeguarding children boards where required and understand their responsibilities and the responsibilities of others in line with the Children Act 2004.
• Having clear procedures followed in practice, monitored and reviewed in place about the use of restraint and safeguarding.
• Taking into account relevant guidance set out in the Care Quality Commission’s Schedule of Applicable Publications
• Ensuring that those working with children must wait for a full CRB disclosure before starting work.
• Training and supervising staff in safeguarding to ensure they can demonstrate the competences listed in Outcome 7E of the Essential Standards of Quality and Safety, Care Quality Commission, London 2010

All children and young people who use services must be
• Fully informed of their care, treatment and support.
• Able to take part in decision making to the fullest extent that is possible.
• Asked if they agree for their parents or guardians to be involved in decisions they need to make.

(Outcome 4I Essential Standards of Quality and Safety, Care Quality Commission,
4. Key Service Outcomes

Evidence is increasing that implementation of the national Quality Criteria for Young People Friendly Services (Department of Health, London 2011) have the potential to greatly improve patient experience, leading to better health outcomes for young people and increasing socially responsible life-long use of the NHS. Implementation is also expected to contribute to improvements in health inequalities and public health outcomes e.g. reduced teenage pregnancy and Sexually Transmitted Infections (STIs) and increased smoking cessation. All providers delivering services to young people should be implementing the good practice guidance which delivers compliance with the quality criteria.

Poorly planned transition from young people’s to adult-oriented health services can be associated with increased risk of non-adherence to treatment and loss to follow-up.
which can have serious consequences. There are measurable adverse consequences in terms of morbidity and mortality as well as in social and educational outcomes. When children and young people who use paediatric services are moving to access adult services (for example, during transition for those with long term conditions), these should be organised so that:

- All those involved in the care, treatment and support cooperate with the planning and provision to ensure that the services provided continue to be appropriate to the age and needs of the person who uses services.

The National Minimum Standards for Providers of Independent Healthcare, (Department of Health, London 2002) require the following standards:

- **A16.1** Children are seen in a separate out-patient area, or where the hospital does not have a separate outpatient area for children, they are seen promptly.
- **A16.3** Toys and/or books suitable to the child’s age are provided.
- **A16.8** There are segregated areas for the reception of children and adolescents into theatre and for recovery, to screen the children and adolescents from adult Patients; the segregated areas contain all necessary equipment for the care of children.
- **A16.9** A parent is to be actively encouraged to stay at all times, with accommodation made available for the adult in the child’s room or close by.
- **A16.10** The child’s family is allowed to visit him/her at any time of the day, except where safeguarding procedures do not allow this
- **A16.13** When a child is in hospital for more than five days, play is managed and supervised by a qualified Hospital Play Specialist.
- **A16.14** Children are required to receive education when in hospital for more than five days; the Local Education Authority has an obligation to meet this need and is contacted if necessary.
- **A18.10** There are written procedures for the assessment of pain in children and the provision of appropriate control.

All hospital settings should meet the Standards for the Care of Critically Ill Children (Paediatric Intensive Care Society, London 2010).

There should be age specific arrangements for meeting Regulation 14 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010.

These require:

- A choice of suitable and nutritious food and hydration, in sufficient quantities to meet service users’ needs;
- Food and hydration that meet any reasonable requirements arising from a service user’s religious or cultural background
- Support, where necessary, for the purposes of enabling service users to eat and drink sufficient amounts for their needs.
- For the purposes of this regulation, “food and hydration” includes, where applicable, parenteral nutrition and the administration of dietary supplements where prescribed.
• Providers must have access to facilities for infant feeding, including facilities to support breastfeeding (Outcome 5E, of the Essential Standards of Quality and Safety, Care Quality Commission, London 2010)

All paediatric patients should have access to appropriately trained paediatric trained dieticians, physiotherapists, occupational therapists, speech and language therapy, psychology, social work and CAMHS services within nationally defined access standards.

All children and young people should have access to a professional who can undertake an assessment using the Common Assessment Framework and access support from social care, housing, education and other agencies as appropriate.

• Ensure the medicines given are appropriate and person-centred by taking account of their age, weight and any learning disability
• Ensure that staff handling medicines have the competency and skills needed for children and young people’s medicines management
• Ensure that wherever possible, age specific information is available for people about the medicines they are taking, including the risks, including information about the use of unlicensed medicine in paediatrics.

Many children with long term illnesses have a learning or physical disability. Providers should ensure that:

• They are supported to have a health action plan
• Facilities meet the appropriate requirements of the Disability Discrimination Act 1995

They meet the standards set out in Transition: getting it right for young people. Improving the transition of young people with long-term conditions from children’s to adult health services. Department of Health, 2006, London
### Change Notice for Published Specifications and Products

developed by Clinical Reference Groups (CRG)

**Amendment to the Published Products**

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<thead>
<tr>
<th>Product Name</th>
<th>Specialised Ear Surgery- Cochlear Implants</th>
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<tr>
<td>CRG Lead</td>
<td>Andrew Reid</td>
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**Description of changes required**

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<th>Describe what was stated in original document</th>
<th>Describe new text in the document</th>
<th>Section/Paragraph to which changes apply</th>
<th>Describe why document change required</th>
<th>Changes made by</th>
<th>Date change made</th>
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<td>The previous year’s specification has been put into the 2014/15 specification template. As a result this has created a new section that needed to be populated linked to the National Outcome Framework and domains</td>
<td>Section 2 and appendix 1</td>
<td>To ensure consistency of specification formatting</td>
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<td>October 2013</td>
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<td>To ensure consistency of format across our specification through ensuring words of scope and IR are included in the exclusion and acceptance area and through using common sub headings</td>
<td>Section 3.4 and sections 3.2 and 3.5</td>
<td>To ensure consistency of specification formatting</td>
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