

B13/S(HSS)/b

**2013/14 NHS STANDARD CONTRACT
FOR NEUROFIBROMATOSIS TYPE 2 SERVICE (ALL AGES)**

SECTION B PART 1 - SERVICE SPECIFICATIONS

Service Specification No.	B13/S(HSS)/b
Service	Neurofibromatosis type 2 service (All Ages)
Commissioner Lead	
Provider Lead	
Period	12 months
Date of Review	

1. Population Needs

1.1 National/local context and evidence base

Historically neurofibromatosis type 2 (NF2) was not clearly delineated from neurofibromatosis 1 (NF1, previously called von Recklinghausen's disease). However, advances in molecular biology and the development of sophisticated imaging techniques confirmed that NF1 and NF2 are distinct conditions both clinically and genetically.

Initially NF2 care was undertaken separately by NF specialists in genetics and neurology clinics or by skull based surgeons looking after patients with sporadic vestibular schwannomas. There was no consensus over the management of vestibular schwannomas with different centres variously advocating early surgical removal, stereotactic surgery or conservative treatment.

Consequent on patient feedback to specialist advisors from The Neurofibromatosis Association (NFA), Professor Evans organised a consensus meeting in 2002 and subsequently published national guidelines for NF2 management (Evans et al 2005b). Despite these the recommendations for one stop multi-disciplinary clinics and a national centre for radiosurgery, many NF2 patients continued to receive ad hoc fragmented care. Furthermore consultants with expertise in sporadic vestibular schwannoma management often fail to recognise the well documented difference in natural history and pathology between sporadic and NF2 related tumours.

Evidence base

A study (Baser et al 2002) of mortality in NF2 showed that being treated in a specialist centre (at that time Cambridge University Foundation Trust, Guys & St.

Thomas' NHS Foundation Trust and Central Manchester University Hospitals NHS Foundation Trust) as being associated with improved survival. This was due largely to the fact that surgeons in these centres recognised the importance of conservative management for many NF2 tumours. All participating centres were co-authors on the peer reviewed guidance recommending the process in sections 4 and 5; the formulation of these guidelines was spearheaded by Prof Evans (British Journal of Neurosurgery 2005).

Manchester was part of the European pilot study of Auditory Brain Stem Implantation published in 2002 (Nevison et al). The whole Manchester series of 60 patients has been presented at international meetings and is submitted for publication. The auditory brainstem implants (ABI) has been shown to be associated with no additional risk to the concurrent removal of a vestibular schwannoma.

The effects of facial weakness are a major issue for patients with NF2. A facial rehabilitation clinic has been set up in Manchester to cater for these patients with ear, nose and throat (ENT), plastic, oculoplastic and physiotherapy support. A patient satisfaction survey of all 136 patients rated the clinic as very useful or excellent (Sadiq et al 2009).

Voice recognition software has been assessed to improve patient communication in the Manchester clinic. This was extremely well received by patients and improved patient communication. Patient satisfaction was high: most said it improved understanding 'completely' or 'mostly' and it was 'much better' compared to other communication support. The professionals were positive about the software's potential. This work received a TrusTech award and was presented at the British Society of Human Genetics in York in 2008 (Belk et al).

The centre at National Centre for Stereotactic Radiosurgery, Sheffield has published its medium term outcomes for NF2 vestibular schwannoma radiosurgery and shown comparable results to surgery (Rowe et al 2002). There remains concern over the possibility of malignant change occurring years after radiation based treatments. The new service will ensure this is closely monitored.

The charity Hearing Concern LINK runs intensive rehabilitation programmes for adults with significant hearing impairment and they have been shown to be of both short and medium term benefit to the patients (Sherbourne et al 2002).

Cost per quality of life for cochlear implants in adults has been validated, but no such analysis has been undertaken in NF2. The mortality benefit from NF2 patients being treated in supra-regional centres is statistically proven and will give rise to better quality and longer life expectancies.

The proposed scanning schedules are the most conservative recommended. It is likely that as each centre becomes more familiar with the different NF2 phenotypes that the scanning schedule will be reduced- particularly in older patients with mild/mosaic disease.

In paediatric cases expert review often results in a decrease in frequency of monitoring MRI scans, as centres with limited experience treat the patients by standard neuro-oncology protocols for malignant central nervous system (CNS) tumours. Furthermore, we have seen unnecessary surgery, particularly on asymptomatic spinal ependymomas by consultants unfamiliar with their natural history in NF2 (they rarely progress to cause symptoms).

2. Scope

2.1 Aims and objectives of service

The overall aim of the service is to provide the highest quality of care to people with Neurofibromatosis type two (NF2). The nationally commissioned service is for coordinated clinical care of all NF2 patients and for surgery/radiosurgery of NF2 related vestibular schwannomas.

Specifically the NF2 service aims:

- to improve the quality and quantity of life of NF2 patients in England
- to increase the number of NF2 patients with serviceable hearing by appropriate timing of surgery or radiotherapy
- to increase hearing rehabilitation by appropriate implantation of a cochlear or brain stem implant
- to reduce loss of function by avoidance of unnecessary surgery
- to deliver high quality holistic care through a multidisciplinary team including: neurologist, neurosurgeon, clinical geneticist, ENT consultant surgeon, ophthalmologist and specialist nursing care
- to provide radiological facilities appropriate to diagnosis and staging of the condition prior to planning treatment
- to provide genetic testing and counselling on mutation types
- to perform appropriate investigations to proceed to surgical treatment options if clinically indicated
- to provide high quality surgical treatment of patients with NF2
- to provide continuous monitoring of risk and governance to ensure that clinical treatment is safe and effective
- to carry out clinical and service audits to ensure highest standards of safety, care and clinical effectiveness.

Objectives

NF2 patients are at risk of deafness as well as a high possibility of facial palsy, visual impairment and loss of muscle function leading to immobility. Management of patients through a specialist service minimises the threat of these disabilities and optimises auditory rehabilitation. The national service ensures that all NF2 patients benefit from a one-stop clinic at which they could see all the necessary specialists in a co-ordinated fashion.

Objectives:

- to enhance quality of life of NF2 patients
- to increase good quality life expectancy of NF2 patients
- to improve the length and duration of serviceable hearing
- once hearing is lost to improve rehabilitation including timely insertion of an appropriate implant
- to improve outcomes of spinal and other surgery and to reduce unnecessary surgery
- to provide an exemplary and comprehensive service for all eligible referred patients with NF2
- expert diagnosis of NF2 utilising the most up-to-date validated diagnostic tools and knowledge
- expert management of patients with NF2 through the use of the most up-to-date clinical protocols and surgical management
- clinically appropriate consideration and provision of surgery within the NF2 patient pathway
- effective monitoring of patients to ensure optimal functioning for the patient with regards to their NF2
- to operate a rolling programme of clinical audit to test current practice and inform the evolution of care in NF2
- to provide care with a patient and family centred focus to maximise the patient experience of care within the nationally designated providers
- to be seen as the leading clinical services and a source of expert advice for the diagnosis and management of NF2 within the NHS
- to support local healthcare providers to manage patients with NF2 whenever it is clinically appropriate and safe to do so
- provide high quality information for patients, families and carers in appropriate and accessible formats and mediums
- to develop the experience, knowledge and skills of the MDT to ensure high quality sustainable provision.

2.2 Service description/care pathway

The national NF2 service designates four centres to provide multidisciplinary clinics where patients can see a number of specialists on the same day. These clinics, based in Cambridge University Hospital NHS Foundation Trust, Guys and St Thomas' NHS Foundation Trust [GSTT], Central Manchester University Hospitals NHS Foundation Trust and Oxford University Hospital NHS Trust, include at least one of each of the following: neuro-otologist, neurosurgeon, neuroradiologist, NF2 physician (geneticist/neurologist), audiologist, and specialist nurse/genetic counsellor with input from ophthalmology, plastic surgery and pain clinics.

The four national centres are based in the following areas and cover the below population:

- Cambridge University Hospital NHS Foundation Trust (11.2 million; 190 patients)

- Guys and St Thomas' NHS FT (13.2million; 224 patients)
- Manchester University Hospitals NHS Foundation Trust (16.7 million; 284 patients)
- Oxford University Hospitals NHS Trust (9.6 million; 164 patients)

The national NF2 centres are commissioned to offer specialist expertise for the main NF2 tumours (Vestibular schwannoma, meningiomas, spinal tumours) and advice regarding management of other complications (ophthalmic and peripheral neuropathy), with two centres providing auditory brainstem implants (ABI) for all appropriate patients in England. Care should be provided in an integrated way and minimise the attendances of patients and their families with services offering one-stop clinics where necessary. The service should support families with transition for their children from paediatric to adult care, raising knowledge and awareness on the management of NF2 and develop extended network links with local hearing, physio- and speech and language therapists.

Nurse co-ordinators employed at each centre will ensure that all NF2 patients and their families are cared for in accordance with published national guidelines and following the national service standard developed with NHS England (NHS CB) team (Evans et al 2005b and appendix).

Currently the four centres manage 317 in total of the projected 862 NF2 patients (37%) in England. Data from Manchester suggest that a significantly greater proportion of complex NF2 patients are seen and managed in the specialty centres.

The service delivers high quality clinical care and surgical treatment to patients with NF2 tumours and will deliver the following service areas:

- Outpatients: multidisciplinary team (MDT) outpatients & satellite outpatients
- Mutation testing for NF2
- ABI and auditory implants
- Vascular surgery
- Stereotactic radiosurgery
- LINK's NF2 course
- Bevacizumab

Patients can be referred from primary care and secondary care. To avoid delay in making the diagnosis, appropriate radiological investigations are usually performed by the designated provider; the case is discussed at the MDT.

The service is configured as a hub and spoke model with specialist centres providing the multidisciplinary clinic (hub) and hold sub-contractual arrangement with the neurosurgical units in their region as satellite clinics (spoke) in the following local areas:

- Birmingham
- Newcastle
- Liverpool
- Plymouth

- Bristol
- Sheffield
- Southampton.

Multidisciplinary (MDT) NF2 clinic The medical, nursing and administrative teams from national centres will work with skull base/neurosurgery units to ensure a cohesive pattern of care for NF2 patients and access to a one-stop clinic. Patients should have the opportunity to be assessed near their home, but their progress will be monitored at least annually via a joint MDT with one of the four centres. Patients can opt to undergo neurosurgery at the unit closest to their home for standard procedures. However, specialist surgery such as cochlear nerve preserving surgery will be carried out at only 4-6 centres in England with appropriate expertise and nerve monitoring. The national providers core MDT includes:

- consultant neurologist
- paediatric neurologist
- neurosurgeons
- paediatric neurosurgeon
- ENT / skull base surgeons
- clinical nurse specialist
- neuroradiologist
- audiologist
- consultant clinical geneticist
- plastic surgeon
- peripheral nerve surgeon
- ophthalmologist.

The MDT will see and review patients by either or both surgical specialties depending on need. Patients will have access to a specialist facial clinic consisting of an oculoplastic surgeon, plastic surgeon and skull base surgeon specifically for problems associated with facial weakness and loss of trigeminal nerve function.

All patients and their families undergo careful genetic assessment and counselling and are reviewed at least once a year within the NF2 MDT. The MDT must have ready access to a full ophthalmological service for patient assessment and advice; team of vestibular and neuro physiotherapists as well as speech and language therapists support the MDT as required.

All patients are reviewed at least once a year in the MDT monthly clinic. The specialist nurses will support patients to understand their diagnosis and the service before meeting with neurosurgeons. Patients are monitored annually with MRI scans to monitor tumour growth. All patients have annual detailed audiometric assessment (if have any measurable hearing) and access to central and local audiological and balance services.

Each designated hub centre will provide a range of clinics / joint clinics e.g.:

- MDT NF2 clinic – neurologist, paediatric neurologist, nurse specialist;
- 'One Stop' clinics for assessment, clinical review, audiology, an eye check

- and access to a hearing therapist;
- Audiology clinic;
- Same day scans and surgical review;
- Genetic testing and counsellor;
- Skull-base clinic.

The NF2 nurse team will work with the neurosurgical units to ensure that all patients have access to MDT clinics. Neurosurgical units should have experience in the treatment of NF2 and conduct at least three MDT clinics of 3-6 patients annually. One neurosurgical unit has already agreed that they will refer all NF2 patients on to their nearest local neurosurgical unit MDT clinic.

Patients with NF2 are at risk of developing multiple tumours in the brain and spine and pose complex management problems and difficult decisions about treatment. At the four specialist centres the clinicians have extensive specialist multidisciplinary expertise in NF2 and will co-ordinate an annual MDT for the units in their region. The MDT will be comprised of the following clinicians; consultant neurosurgeon, consultant ENT surgeon, consultant clinical geneticist/neurologist, Specialist Clinical Genetics Nurse, consultant neurosurgeon with a specialist interest in stereotactic radiosurgery. This MDT clinic is supported by a specialist supra-regional skull base MDT structure incorporating dedicated neuroradiology, specialist pathology, audiology, and plastics/ maxillofacial/ ophthalmological surgery.

Genetic counselling Children at risk of NF2 are managed through the genetic NF clinic. Preliminary counselling is usually done by the NF2 genetic counsellor at a Home visit. Genetic testing is offered around the age of ten and those with the abnormal gene then commence annual scans/audiology. They are introduced to the main clinic as and when investigation results merit.

For some patients who are close to the centre and who prefer not to have all their work on a single day a two day approach may be employed. The multidisciplinary teams will be coordinated by a clinician(s) with a special interest in the holistic care of patients with NF2.

Auditory rehabilitation Patients are offered hearing rehabilitation and the opportunity to discuss auditory brainstem implantation within the environment of the hearing implant unit with a highly experienced team of audiological scientists and hearing rehabilitation therapists. NF2 patients will have an implanted with a cochlear implant if their cochlear nerve is intact ABI can be insertion during surgery for vestibular schwannomas or as a separate surgical procedure. All Auditory Brainstem Implant procedures will be carried out by one of two designated surgeons.

Surgery The specific surgery funded though the service is for vestibular schwannomas and cochlear and ABI implants. However, it is anticipated that the majority of NF2 related surgeries will be in the designated centres or satellites. On occasions there will be the need for urgent local neurosurgical assessment (e.g. blocked shunt). In addition each of the four centres has funded MDT outpatient advice re facial nerve palsy and peripheral schwannoma management.

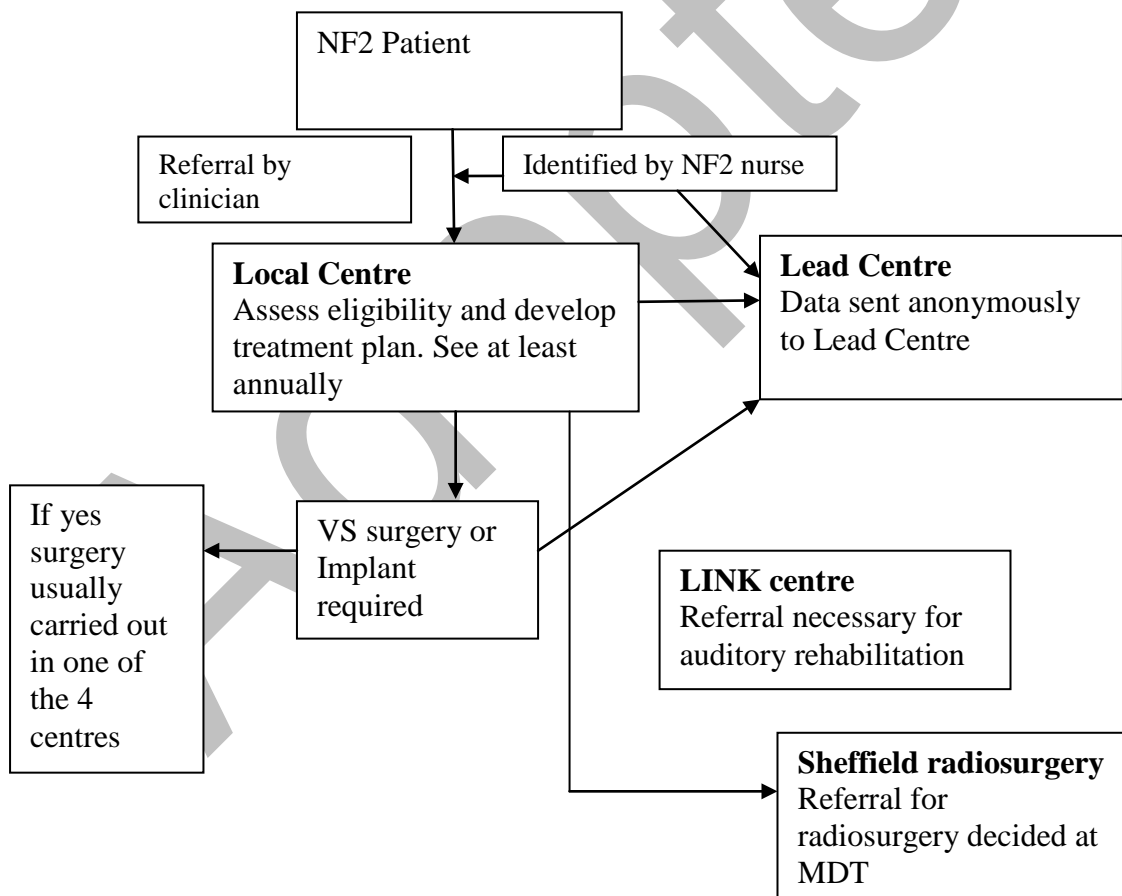
Stereotactic radiosurgery Patients are offered stereotactic radiosurgery for the treatment of NF2 tumours where clinically appropriate in Sheffield. Risk of radiation induced malignancy is to be monitored closely by the service.

The majority of radiation based treatments will be in Sheffield and those done elsewhere will be monitored pre- and post-operatively by a standard protocol. Unproven radiotherapy treatments in the context of NF2 such as fractionated radiotherapy should only be undertaken as part of a fully registered clinical trial.

LINK course intensive rehabilitation programmes for adults with significant hearing impairment.

Bevacizumab Assessment and management of bevacizumab for patients with rapidly growing Vestibular Schwannomas following the current National Protocol.

A sequential flow diagram of the integrated service user pathway(s) showing access, transfer and exit points, potential routes and relationships with other health and/or social care providers is set out below:



Days/hours of operation

Inpatient care will be provided 24 hours a day, 365 days a year.

Outpatient care and home visits will be provided through the normal working day. MDT clinics will be on a specified day of the week and run monthly.

Discharge Planning:

Criteria for discharge from care:

- no further investigation required
- no adverse outcomes anticipated
- clinically appropriate arrangements for local care and NF2 service follow-up have been discussed and agreed by all relevant parties
- parents/carers have demonstrated competence in any care they will be required to provide in relation to NF2
- parent /carers understand and have the necessary information to contact their nationally designated NF2 provider.

All discharge planning will be managed by the skull base and oncological surgeons in charge of the case with local health and social care providers being fully informed of the patient's condition and any responsibilities they will have to assume. This will be formalised in written communication to the patient's GP and all other relevant parties.

2.3 Population covered

This service covers patients registered with an English General Practitioner, residents in Scotland and residents in the European Union and eligible for treatment in the NHS under reciprocal arrangements. Patients from Wales and Northern Ireland are not part of this commissioned service and the Trust must have separate arrangements in place.

The projected number of English patients in each category are shown in the table below:

Category	Total England (projected)
NF2 patients (total)	866
Mosaic	173
Children with symptoms	47
Classical (mild to moderate) adults	355
Severe adults	260
Asymptomatic gene tested children	31
At risk	120

2.4 Any acceptance and exclusion criteria

Referral criteria, sources and routes

The treatment of type 2 neurofibromatosis represents a lifetime commitment to the maintenance of health, conservation of function and quality of life. Any patient fulfilling Manchester criteria for NF2 (Evans et al 1992a, Baser et al 2002) or who has been identified with a disease causing mutation in the NF2 gene will be eligible.

All patients with a confirmed diagnosis of NF2 using the criteria below will be referred to the service:

- bilateral vestibular schwannomas
- 1st degree family relative with NF2 and unilateral vestibular schwannoma or any two* of: meningioma, schwannoma, glioma
- neurofibroma, posterior subcapsular lenticular opacities
- unilateral vestibular schwannoma and any two of: meningioma, schwannoma, glioma, neurofibroma, posterior subcapsular lenticular
- opacities
- multiple meningiomas (two or more) and unilateral vestibular schwannoma or any two of: schwannoma, glioma, neurofibroma, cataract

*Any two or refers to two individual tumours or cataract. (Individuals shown to carry a pathogenic mutation in the NF2 gene will also be included).

Confirmation of an NF2 diagnosis may simply require a cranial MRI scan. However, in other cases confirmation will be necessary by a combination of clinical assessment, whole craniospinal axis imaging with MRI and molecular testing.

Routes

It is envisaged that patients will be referred from multiple sources but primarily from either ENT surgeons, neurosurgeons, neurologists, clinical geneticists or paediatricians.

Referrals will be accepted from any clinician with MRI imaging of the cranium being a minimal requirement. All referrals will be assessed for eligibility for the NF2 service by the lead clinician and study nurse and patients will be assessed at the next available MDT clinic.

Exclusion criteria

Individuals with NF2 related tumours, but not fulfilling NF2 criteria above. There will be no age or other health related exclusion. In order to exclude NF2 in patients who have a very early diagnosis of NF2 related tumour (vestibular schwannoma <30 years or meningioma <20 years) or two NF2 related tumours at any age, molecular testing of blood and tumour material is advised via the NGRL in Manchester.

Any patient not fulfilling the eligibility criteria that has not had full assessment with the following will be seen to assess eligibility:

- cranial MRI with 3mm cuts through Internal auditory meatus
- spinal MRI
- cutaneous examination by an experienced NF2 clinician
- ophthalmic examination for cataracts and retinal haemangioma
- blood and when available tumour DNA analysis for NF2.

Response time & detail and prioritisation

Initial telephone contacts from referrers are to be dealt with immediately by the senior clinical lead/surgeon. The referral may be accepted over the phone immediately and/or the NF2 service provider may request the referrer to carry out further investigations. Advice on optimal management will be given and on-going support will be provided until the patient is transferred.

Transfer of patients to a nationally designated NF2 service will be prioritised according to the needs of individual patients but in all cases where a transfer to the NF2 service has been agreed that transfer will take place as soon as is practicable. If necessary the nationally designated NF2 providers will communicate with each other to coordinate appropriate care for patients at times when capacity at one or both the providers is under pressure.

The service is accessible to all patients with a suspected NF2 regardless of sex, race, or gender. Providers require staff to attend mandatory training on equality and diversity and the facilities provided offer appropriate disabled access for patients, family and carers. When required the providers will use translators and printed information is available in multiple languages. Special provision will be made for children with NF2.

The provider has a duty to co-operate with the commissioner in undertaking Equality Impact Assessments as a requirement of race, gender, sexual orientation, religion and disability equality legislation.

2.5 Interdependencies with other services

Internally the NF2 team will link into multiple clinical and administrative teams as a result of the composition of the broad MDT.

The NF2 service will be responsible for oversight of all aspects of patient care for every NF2 patient in England.

The service will determine need for and carry out or commission all of the following procedures:

- Auditory Brain Stem Implantation (two surgeons maximum)
- Stereotactic Radiosurgery
- Vestibular schwannoma surgery.

External to this the nationally designated NF2 providers are the leaders in the NHS for patient care in this area. They provide a direct source of advice and support

when other clinicians refer patients into the nationally designated providers. This support will continue until the patient is transferred into the nationally designated provider or it becomes apparent that the patient does not have a NF2.

The nationally designated providers also provide education within the NHS to raise and maintain awareness of NF2 and its management.

The national providers will form a relationship with local health and social care providers to help optimise any care for NF2 provided locally for the patient. This may include liaison with consultants, GPs, community nurses or social workers etc.

Relevant networks and screening programmes - There are no national/clinical networks/expert patient programmes and screening programmes applicable to the service.

3. Applicable Service Standards

3.1 Applicable national standards e.g. NICE, Royal College

The nationally designated NF2 providers must be fully integrated into their trust's corporate and clinical governance arrangements and must fully comply fully with Clinical Negligence Scheme for Trusts (CNST) and Care Quality Commission (CQC) requirements in terms of quality and governance. The hub centres are responsible for overseeing the governance arrangement of any spoke clinic provided under sub-contractual arrangements.

Each centre will ensure that there are:

- regular meetings with patient representatives
- all practitioners will participate in continuous professional development and networking
- patient outcome data is recorded and audited across the service.

The commissioners and service will conduct a formal Joint Service Review at least every six months. All centres must participate in the national audit commissioned by NHS England - audit meetings should address:

- clinical performance and outcome
- process-related indicators, e.g. efficiency of the assessment process, prescribing policy, bed provision and occupancy, outpatient follow up etc
- stakeholder satisfaction including feedback from patients, their families, referring surgeon and General Practitioners.

See also NHS England Service Standards for Multidisciplinary Service for diagnosis and management of Neurofibromatosis Type 2 (NF2)

4. Key Service Outcomes

These outcomes will be ensured by patient centred care by multidisciplinary teams. Each patient at presentation/diagnosis and then annually (100% data completeness).

The main outcome measures we will monitor are:

- length of time that useful hearing as measured by speech discrimination is maintained in at least one ear from date of diagnosis. (Speech discrimination of >60%);
- facial palsy rates of <20% as measured by House Brackmann scores of 4-6 18 months post surgery for vestibular schwannoma;
- proportion of full time users of an Auditory Brain Stem Implant or cochlear implant of those who would otherwise have no useful hearing. Expected that >80% will be full time users;
- reduction in disease related mortality;
- timing between presentation of symptoms and surgical intervention.

5. Location of Provider Premises

Location of service

The service is delivered across England by four designated centres for the national caseload. Designated services are based at:

- Cambridge University Hospitals NHS Foundation Trust
- Central Manchester University Hospitals NHS Foundation Trust
- Guy's & St Thomas' NHS Foundation Trust
- Oxford University Hospitals NHS Trust.

Sub-contractors

- The charity Hearing Concern LINK, Eastbourne LINK run intensive rehabilitation programmes for adults with significant hearing impairment. Centres to provide up to 15 courses per year.
- National Centre for Stereotactic Radiosurgery, Sheffield Centres to hold sub-contract arrangements with National Centre for Stereotactic Radiotherapy, Sheffield for the treatment of NF2 tumours with stereotactic radiosurgery - contract up to 12 radiosurgical procedures on NF2 patients annually.
- Satellite Clinics with providers in Birmingham, Newcastle, Liverpool, Plymouth, Bristol, Sheffield and Southampton

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