Clinical Commissioning Policy Proposition:
Bone conducting hearing implants (BCHIs) for hearing loss (all ages)

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Clinical Commissioning Policy Proposition: Bone conducting hearing implants (BCHIs) for hearing loss (all ages)

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Plain Language Summary

Hearing loss affects over 10 million people across the United Kingdom and can lead to significant health and mental health issues. The first and preferred way of correcting hearing loss is to use a conventional hearing aid that simply amplifies sound into the ear canal, making it louder. For some patients, these regular hearing aids will not work or they are not suitable, either due to the anatomy of the ear or due to medical conditions affecting the ear.

For these patients, a bone conducting hearing implant may provide a better solution to their hearing loss. Bone conducting hearing implants include both bone conducting hearing devices (BCHDs) and middle ear implants (MEIs).

This policy aims to define NHS England's commissioning position for bone conducting hearing implants, including BCHDs and MEIs, and define the associated pathway.

The care of all adults and children considering hearing implantation should be coordinated by a multidisciplinary team (MDT), including a specialised ENT surgeon, specialised audiologist and rehabilitation experts. Additionally there should be a separately coordinated MDT or team approach for children with microtia. These MDTs need to consider which implant is most suitable for each patient, taking into account various factors.

NHS England has concluded that there is sufficient evidence to support the routine commissioning of bone conducting hearing implants for adults and children with hearing loss.

1. Introduction

This document describes the evidence that has been considered by NHS England in formulating a proposal to routinely commission bone conducting hearing implants.

This document also describes the proposed criteria for commissioning, proposed governance arrangements and proposed funding mechanisms.

For the purpose of consultation NHS England invites views on the evidence and other information that has been taken into account as described in this policy proposition.

A final decision as to whether bone conducting hearing implants will be routinely commissioned is planned to be made by NHS England by June 2016 following a recommendation from the Clinical Priorities Advisory Group.

2. The proposed intervention and clinical indication

It is estimated that 1 in 6, approximately 10 million, people in the UK have some degree of hearing impairment (Action on Hearing Loss, 2011). Deafness may impact on all aspects of an individual's life through reducing their ability to communicate and integrate with family, friends and the broader community. It can affect health, education, employment and recreational activities. An impact upon mental health is not unusual, with increased prevalence of dementia, anxiety and depression with in the deaf population.

The first, and preferred, method of rehabilitating hearing loss is to use conventional air conduction hearing aids (ACHA). There are various models of ACHAs. The principle is to transmit amplified sound down the ear canal to the ear drum (tympanic membrane) via the ossicles and hence to the inner ear (cochlea). If an ACHA does not provide adequate benefit then an appropriate implantable hearing device should be considered.

Bone conducting hearing implants (BCHIs) include both bone conducting hearing devices (BCHDs) and middle ear implants (MEIs).

BCHDs bypass the outer and middle ear, delivering sound waves directly to the inner ears. Such devices can be fitted to spectacles or held in place with a headband. Surgical interventions can result in percutaneous or transcutaneous devices being implanted depending on appropriate selection and assessment.

Middle ear implants are surgically implanted electronic devices which aim to correct hearing loss through stimulation of the cochlea by delivering sound energy to the ossicles or directly to the entrance of the cochlea (oval or round window placement). Middle ear implants are placed into the middle ear and generally leave the external auditory canal open and unobstructed. A middle ear implant differs from a cochlear implant in that the latter directly electronically stimulates the auditory nerve.

Some of these devices have been in regular clinical use for over 30 years. For a relatively small number of patients with hearing loss BCHIs are the only option for restoration of hearing, and one of the aims of this document is to bring together more effective clinical commissioning of the improving technologies.

3. Definitions

Depending on the configuration of the hearing loss, patients can be classed as having;

- **Sensorineural hearing loss** is due to damage in the one or both cochleas, the auditory nerve or the auditory centres in the brain. This may be permanent or non-permanent depending on the cause.
- **Conductive hearing loss** is due to difficulties in the transmission of sound through one or both external ears/middle ears to the inner ear. In a conductive hearing loss the cochlea works normally, therefore, conductive hearing losses can sometimes be improved by conventional surgical treatment to the external/middle ear.
- **Mixed hearing loss** is a combination of conductive and sensorineural hearing loss in one or both ears.
- **Unilateral hearing loss** which may be conductive, mixed or sensorineural hearing loss, or asymmetric hearing loss. These configurations of hearing loss can cause problems in localising sound and hearing in background noise. A unilateral profound sensorineural hearing loss with normal hearing on the contralateral side is also sometimes referred to as single sided deafness (SSD).

Bone conducting hearing implants (BCHIs) comprise both bone conducting hearing devices (BCHDs) and middle ear implants (MEIs).

Bone conducting hearing devices (BCHDs) are types of hearing implant which typically use both internal (implanted) and external components working together to improve hearing via bone conduction. Soundwaves travel directly to the inner ear and nerves of hearing through the bone, bypassing the outer and middle ear. Surgical BCHDs are categorised into percutaneous or transcutaneous systems which can be active or passive; however there are currently no active percutaneous systems.

- Passive percutaneous systems require the surgical placement of a titanium implant and an abutment fitting, which penetrates the skin (percutaneous). Following the osseointegration of these components, the audio processor is directly placed on to the abutment. The audio processor transmits vibrational sound energy to the skull bone directly without any attenuation from the skin.
- Passive transcutaneous systems transmit vibration through the skin and are functionally similar to a softband or test band, but relying on an implanted magnet for sound processor retention. This is also termed ‘skin drive’
- Active transcutaneous systems have the transducer implanted in direct contact with the bone (direct drive) without any loss due to skin attenuation.

Middle Ear Implants (MEIs) systems rely on transducers connected to the ossicular chain, replacing a part of the ossicular chain, or directly coupled to the round window or other cochlea structure. They can be subdivided into semi-implantable and fully implantable systems.

- The semi-implantable systems feature an external processor magnetically held in place to the internal active implant. The transducer can be surgically attached to

the incus, stapes, oval or round window depending on middle ear pathology.

- Fully implantable MEIs feature a sound processor which is implanted beneath the skin. In some systems a microphone is also implanted beneath the skin, and in others the movement of the tympanic membrane is monitored to determine the acoustic input to the ear.

Not fitting into any specific category is oral bone conduction via the teeth. This does not require surgical implantation but consists of a microphone in the ear connected to a sound processor behind the ear which transmits signals to a dental device which produces bone conduction vibrations.

4. Aim and objectives

This policy proposition aims to define NHS England's commissioning position on bone conducting hearing implants as part of the treatment pathway for adults and children with hearing loss.

The objective is to ensure evidence based commissioning with the aim of improving outcomes for adults and children with hearing loss.

5. Epidemiology and needs assessment

Aetiologies of conductive hearing impairment

Action on Hearing Loss estimate that 3.7 million people of working age in the UK have a hearing loss, increasing to 6.4 million over retirement age. Therefore, a prevalence of 704,000 people in the UK with a conductive hearing loss can be inferred. BCHDs and MEIs are only appropriate for a very small sub-set of these patients.

The conditions that commonly require BCHI include:

- **Atresia/Microtia**: The incidence of congenital atresia/microtia is approximately 1:10,000 live births. In 2014 there were 695,233 live births in England and Wales (Office of National Statistics). This would represent approximately 70 cases per year. Not all would require pinna reconstruction but all would require auditory support.
  - Syndromes likely to include atresia/microtia include Treacher Collins syndrome, Goldenhaar syndrome & Crouzon syndrome.

- **Otitis media**: The incidence of chronic suppurative otitis media is 1-2% in adults, and 4.76% in children, with up to half of cases being bilateral. Relatively few of these cases will require BCHI.
  - Syndromes likely to include otitis media include Down syndrome, and CHARGE syndrome.

- Other conditions that more rarely require consideration of BCHI include Otitis externa, bilateral sensorineural hearing impairment with additional ear canal stenosis or ear mould allergy, and unilateral hearing impairment.
  - Data from the Newborn Hearing Screening Program suggests that the prevalence of unilateral permanent hearing loss at birth is 0.61 per 1000 across the population (although this figure is higher for children in at risk groups). Prevalence of adult unilateral hearing impairment is unknown, but can be acquired following a number of conditions including acoustic neuroma excision, Meniere`s disease and sudden idiopathic sensorineural hearing loss.

Surgical interventions for Bone Conduction devices have been performed since the early 80s. In Hospital Episode Statistics (HES) data during 2014/15 c. 1,145 episodes relating to BCHI procedure codes were identified.

6. Evidence base

NHS England has concluded that there is sufficient evidence to support a proposal for the routine commissioning of bone conducting hearing implants (BCHIs), including BCHDs and MEIs, for adults and children with hearing loss. While it is acknowledged that there is no level 1 evidence for the use of BCHIs in these population groups, there is a strong rationale for commissioning these interventions for the following reasons:

1. As noted in section 2, these interventions have been in regular clinical use for over 30 years;
2. NHS England already routinely commissions these interventions;
3. For a relatively small number of patients with hearing loss, BCHI's are the only option for restoration of hearing; and
4. For these clinical conditions it is not appropriate to have randomised control trials (RCTs) as there are no other alternatives if acoustic hearing aids cannot be used effectively.

To support this policy, two evidence reviews have been conducted for both BCHDs and MEIs. The initial evidence review was conducted in October 2014 and an update provided in February 2016.

Evidence base for BCHDs

Evidence summary – October 2014

1. Are the following bone-conduction hearing devices: (i) transcutaneous e.g. Sophono, BAHA 4 Attract, (ii) Bonebridge, (iii) SoundBite clinically effective in people with hearing impairment compared with no intervention or with any other hearing device?[1]

[1] Whilst the clinical evidence review has considered specific devices as comparators, the policy is device and manufacturer agnostic.

The transcutaneous bone conduction hearing devices Sophono, BAHA 4 Attract and Bonebridge appear to be clinically effective compared to no intervention, but this is based on a few, small studies. PTA improved by between 19 dB and 43 dB, SRT improved by 19 dB to 36.25 dB and WRS at 65 dB improved by between 59.2% to 84.1%. Quality of life improvements ranged from +42 on GBI, +45 on GCBI and 79% on HDSS. No studies were identified of high enough quality to determine their clinical effectiveness compared to any other hearing device. Safety issues include MRI limitations and potential to cause pain and damage to the skin overlying the implant.

SoundBite was found to be clinically effective in three small case studies according to subjective questionnaire results, the APHAB score was between 64% and 77%, but objective audiological evidence was either inconsistent or lacking. No studies were identified of high enough quality to determine their clinical effectiveness compared to any other hearing device. No major safety concerns were reported in the limited case studies identified.

Evidence summary – February 2016

1. Are the following bone-conduction hearing devices clinically effective in people with hearing impairment compared with no intervention or with any other hearing device?
(i) Transcutaneous e.g. Sophono, BAHA 4 Attract
(ii) Bonebridge
(iii) SoundBite

There is some evidence for the clinical effectiveness of the transcutaneous bone-conduction hearing devices BAHA® Attract, Sophono® Alpha and Bonebridge™ compared to no intervention (unaided). However this evidence is based on a few very small unrandomised studies and the statistical information on the observed improvements on quality of life or activities was generally not reported. There is evidence from small studies to suggest that there is no difference in the improvements achieved in aided thresholds or speech discrimination scores between BAHA® Attract and Sophono® Alpha. However these findings are based on indirect comparison. Sophono® Alpha appears to be as effective as percutaneous BAHA® while one study suggests that percutaneous BAHA® is more effective than the BAHA® Attract.

One study of the use of SoundBite™ found that the device had no effect on hearing threshold but improved APHAB scores compared with the unaided situation.

2. Are the following bone-conduction hearing devices cost-effective in people with hearing impairment compared with no intervention or with any other hearing device?
(i) Transcutaneous e.g. Sophono, BAHA 4 Attract
(ii) Bonebridge
(iii) SoundBite

We did not identify any studies on the cost-effectiveness of bone-conduction hearing

devices.

Evidence base for MEIs

Evidence summary – October 2014

1. Are middle ear implants clinically effective in children and adults with moderate to severe sensori-neural, mixed or conductive hearing loss compared with conventional hearing aids, bone anchored hearing aids or cochlear implants?

Overall, there is a lack of high-level, high quality evidence investigating the effectiveness of middle ear implants in both children and adults. Evidence identified was from the findings of systematic reviews of non-randomised comparative studies and case series (both children and adults). No randomised studies were found.

There is considerable heterogeneity in the available studies regarding patient enrolment, study design, intervention, comparator, length of follow-up and outcome measures. The studies comprise small numbers of patients with a range of severities of hearing loss, which made meaningful reporting of outcomes difficult.

In studies of children and mixed populations of children and adults, air conduction thresholds and speech recognition appeared to improve with MEIs compared with the unaided post-operative condition. Some improvements were also reported with MEI compared to pre-operative conditions however it was not always clear whether the pre-operative condition was aided or unaided.

In adults, there was some evidence demonstrating that MEIs appear to be effective in improving hearing and speech discrimination from unaided conditions in patients with sensori-neural neural hearing loss, mixed hearing loss and conductive hearing loss. There was also some evidence that speech discrimination in quiet and in noise was at least as good as the external hearing aid.

Patient reported outcomes were not reported in the studies of children only. In the mixed population studies, patients appeared to be generally satisfied with their MEIs and one study reported improvements in ease of communication and listening under reverberant conditions compared to the unaided post-operative condition. In the adult only studies, improved sound quality, canal occlusion, feedback and quality of life were reported compared with an external hearing aid.

The MEI appears to be associated with loss of residual hearing post implantation. The majority of complications reported were rare and of low severity. However, safety and in particular safety relative to other therapies, has not been well studied.

There are a number of factors that determine suitability for middle ear implants. The patient’s inner ear must be sufficiently anatomically intact to allow for manipulation of the device and the patient must be fit for surgery. Patients must be fully informed of all their options and the potential complications that are associated with each

option.

Larger centres would support the development of surgical skill and the opportunity to practice more than one approach to implantation as several as described in the literature. Choice of approach may be influenced by the individual anatomy of the patient.

2. Are middle ear implants cost effective in children and adults with moderate to severe sensori-neural, mixed or conductive hearing loss compared with conventional hearing aids, bone anchored hearing aids or cochlear implants?

We found insufficient evidence to answer this question.

Evidence summary – February 2016

1. Are middle ear implants clinically effective in children and adults with moderate to severe sensori-neural, mixed or conductive hearing loss compared with conventional hearing aids, bone anchored hearing aids or cochlear implants?

Overall, there is a paucity of high-level evidence from which firm conclusions on the relative effectiveness of MEIs can be drawn. We did not find any randomised studies. Evidence of effectiveness was from systematic reviews of non-randomised comparative studies and case series and from primary non-randomised comparative studies and case series (both children and adults).

Generally, the studies of MEIs in children and adults reported improvements in both functional gain and speech outcomes. However, statistical analyses were often not supplied. Quality of life and patient satisfaction outcomes showed benefits when reported although these were not uniformly reported across the studies.

The studies were very variable with regards to patient enrolment, study design, intervention, comparators, outcome measures and length of follow-up. The studies were very small and included patients with a range of severities and types of hearing loss, and in studies of children, a range of underlying causes of hearing loss, which made meaningful reporting of outcomes difficult.

The MEI appears to be associated with loss of residual hearing post implantation although there is some evidence to show that bone conduction (BC) thresholds were preserved after implantation and there is no indication of an increase in the small air-bone gaps introduced by the implantation over time. The majority of other complications reported were rare and of low severity. However, safety and in particular safety relative to other therapies, has not been well studied.

2. Are middle ear implants cost effective in children and adults with moderate to severe sensori-neural, mixed or conductive hearing loss compared with conventional hearing aids, bone anchored hearing aids or cochlear implants?

We did not identify any studies of the cost-effectiveness of MEIs for hearing loss in children or adults.

7. Proposed criteria for commissioning

BCHDs and MEIs will only be available to patients for whom:

(1) Conventional air conduction hearing aids (ACHA) are not suitable, or do not provide adequate benefit (see patient pathway); AND

(2) Patients have a level of hearing loss that falls within BCHD and MEI manufacturer's guidelines.

The specific criteria for BCHDs and MEIs are outlined below.

BCHDs

Implanted BCHDs are commissioned for use in adults and children as per manufacturers CE markings who have:

(1a) Unilateral or bilateral conductive or mixed hearing loss within the manufacturers fitting criteria; AND

Stable bone conduction thresholds (≤15 dB deterioration in >2 frequencies in a 2 year period).

OR

(1b) Unilateral sensorineural hearing impairment (including single-sided deafness (SSD)) where the better ear has bone-conduction hearing thresholds within the manufacturers fitting criteria including SSD;

AND

(2) Trialled an ACHA or wireless CROS / BiCROS hearing aid for a minimum of 4 weeks, or who are anatomically or physiologically unable to undertake a trial of an ACHA;

AND

(3) Trialled a BCHD on a softband or headband for a minimum of 14 days and show benefit in speech tests.

BCHDs will not be commissioned for:

- Patients with a bone disease that is unable to support an implant
- Patients who have a sensitivity or allergy to the materials used.
- Patients with physical, emotional or psychological disorders that, despite suitable treatment and support, would interfere with surgery or the ability to allow suitable rehabilitation such that significant benefit would be unlikely.

BCHDs should be used with particular caution in patients who have had radiotherapy to the area of bone to be implanted and also in those patients who have a bone disease that affects the strength and integration integrity of an implant.

In these patient groups the decision pathway and care should be undertaken by an auditory implant centre MDT.

The use of a device outside of the manufacturers specifications is not routinely commissioned unless part of a recognised and approved trial supported by suitable funding.

Centres implanting BCHDs should aim not to implant devices at the upper range of their fitting range, as this is unlikely to offer long-term benefit to the patient.

Where a candidate is suitable for more than one BCHD device, the most cost effective option must be selected by the MDT with full patient involvement

MEIs

MEIs are commissioned for use in adults and children > 5 years of age (or as per manufacturers CE markings) who have:

(1) Unilateral or bilateral conductive, mixed or sensorineural hearing loss within the manufacturers fitting criteria;

AND

(2) Normal middle ear function / anatomy determined by tympanometry and acoustic reflexes and CT imaging;

AND

(3) Stable bone conduction thresholds (≤15 dB deterioration in >2 frequencies in a 2 year period);

AND

(4) Trialled an ACHA or wireless CROS / BiCROS hearing aid for a minimum of 4 weeks, or who are anatomically or physiologically unable to undertake a trial of an ACHA.

MEIs will not be commissioned for:

- Patients with a recent history of uncontrolled middle ear infections.
- Patients who have a sensitivity or allergy to the materials used.
- Patients with physical, emotional or psychological disorders that, despite suitable treatment and support, would interfere with surgery or the ability to allow suitable rehabilitation such that significant benefit would be unlikely.

The use of a device outside of the manufacturers specifications is not routinely commissioned unless part of a recognised and approved trial supported by suitable funding.

Where a candidate is suitable for more than one MEI device, the most cost effective

option must be selected by the MDT with full patient involvement

BCHIs will be routinely commissioned by NHSE when assessment by a multidisciplinary team leads to a clear recommendation of a BCHD or MEI. BCHIs may be fitted bilaterally providing the above standards are met.

8. Proposed patient pathway

Diagnosis:

Individuals suspected of having a hearing loss are most typically referred by their GP for a full audiometric evaluation of their hearing. Upon the diagnosis of a hearing loss conventional ACHAs will be trialled for up to 3 months where appropriate. If the ACHAs provide sufficient benefit then the patient will continue using these.

When ACHAs do not provide adequate benefit (e.g. with chronic discharge, ACHAs cannot be fitted due to a medical condition in the ear or when the hearing aid gain is not sufficient to overcome the hearing loss), individuals will be assessed for hearing implant candidacy. This also applies to existing ACHAs users who have hearing levels which deteriorate or change, resulting in reduced benefit from their ACHAs. These patients will be referred for a further assessment at a hearing implant centre.

Assessment by MDT:

Upon referral to a hearing implant centre, patients will be fully assessed. If the most appropriate ACHA setup is not suitable for the patient, then a hearing implant will be considered.

- Audiological assessments may include otoscopy, tympanometry, age-appropriate hearing assessments, re-assess original hearing aid fitting with real ear measurements, consider use of wireless contralateral routing of signal (CROS) or binaural CROS (BiCROS) aids, and hypoallergenic ear moulds, speech testing in quiet, in noise and objective hearing assessments as appropriate.

- Patient / family / carer understanding and expectations of implantation and informed consent.

- Medical assessments (clinical history, physical examination, fitness for surgery, suitability of anatomical site for implantation, MRI/ CT scan as required). Assessments for the hearing rehabilitation of children with microtia will be coordinated with the views of the wider team responsible for the cosmetic aspects of care.

Trial of device:

Upon completion of these further investigations, the specialist audiology MDT will

decide if the patient is best suited to a BCHD, MEI, cochlear implant or no device. If the MDT decide a BCHD or MEI are indicated the patient will then undergo a 14 day trial (minimum) with an appropriate device that is eventually used in post-surgical fitment (i.e. a head band on a loan device in the relevant home, social, work and learning environments). This trial will be supported by suitable tools for assessment of benefit by the patient including pre- and post- trial evaluations e.g. validated outcome questionnaires such as the client oriented scale of improvement (COSI), Glasgow hearing aid benefit profile (GHABP) or Bern Benefit in Single-Sided Deafness Questionnaire. Prolonged BCHD use on softband, testband or other device may be appropriate for some children and adults as part of management.

As part of the assessment process, patients who may be candidates for hearing implants and their families / carers, will receive information about voluntary services and support groups including the opportunity to have contact with deaf patients of a similar age (and their families for paediatric patients) who are users of hearing 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, following the above assessments and device trial period, the MDT decide the patient is suitable to receive a unilateral or bilateral hearing implant(s), the most appropriate device(s) is selected and they will be given a date for implantation.

If, at any stage in the MDT assessment, it is determined that patients are not suitable for a hearing implant, the service will ensure that:
- The patient and/or the family have the opportunity to discuss the outcome of the assessment, including the reasons why an implant is deemed unsuitable.
- The referrer, the local audiology department, other relevant professionals and the patient's General Practitioner (GP) are notified of the decision and the future management plan.

Implantation:

The in-patient episode will include the following:
- The operation – completed by an experienced, specialist Ear Nose and Throat (ENT) Consultant Surgeon. Implantation must be carried out by appropriately qualified surgeons who have an adequate caseload to maintain surgical skills and optimise outcomes.

- Provision of written information regarding care of the wound/ear and pain management post operatively

- Provision of guidelines on what to do should medical /surgical problems arise.

- Advice regarding health and safety with a hearing implant

Post-implantation follow up and on-going support will include:

- The patient will have access to more intensive rehabilitation needs including:

- Medical check following implantation of surgical site and device placement and functioning.
- MEI patients require a pure-tone audiogram to determine stability of hearing following surgery, at the time of processor activation.
- Activation and programming of device using in situ measurements will be performed at the initial fitting appointment. Verification of the amplification of sound will also be performed e.g. speech testing and adjusted when it is not optimal.

• On-going sound programming and assessment dependent on individual need.

• Regular audiological review, typically annually in the first instance.

• Training and advice to patient (and carers if appropriate) on care and use of the implant, simple trouble-shooting and maintenance and visual inspection of external parts.

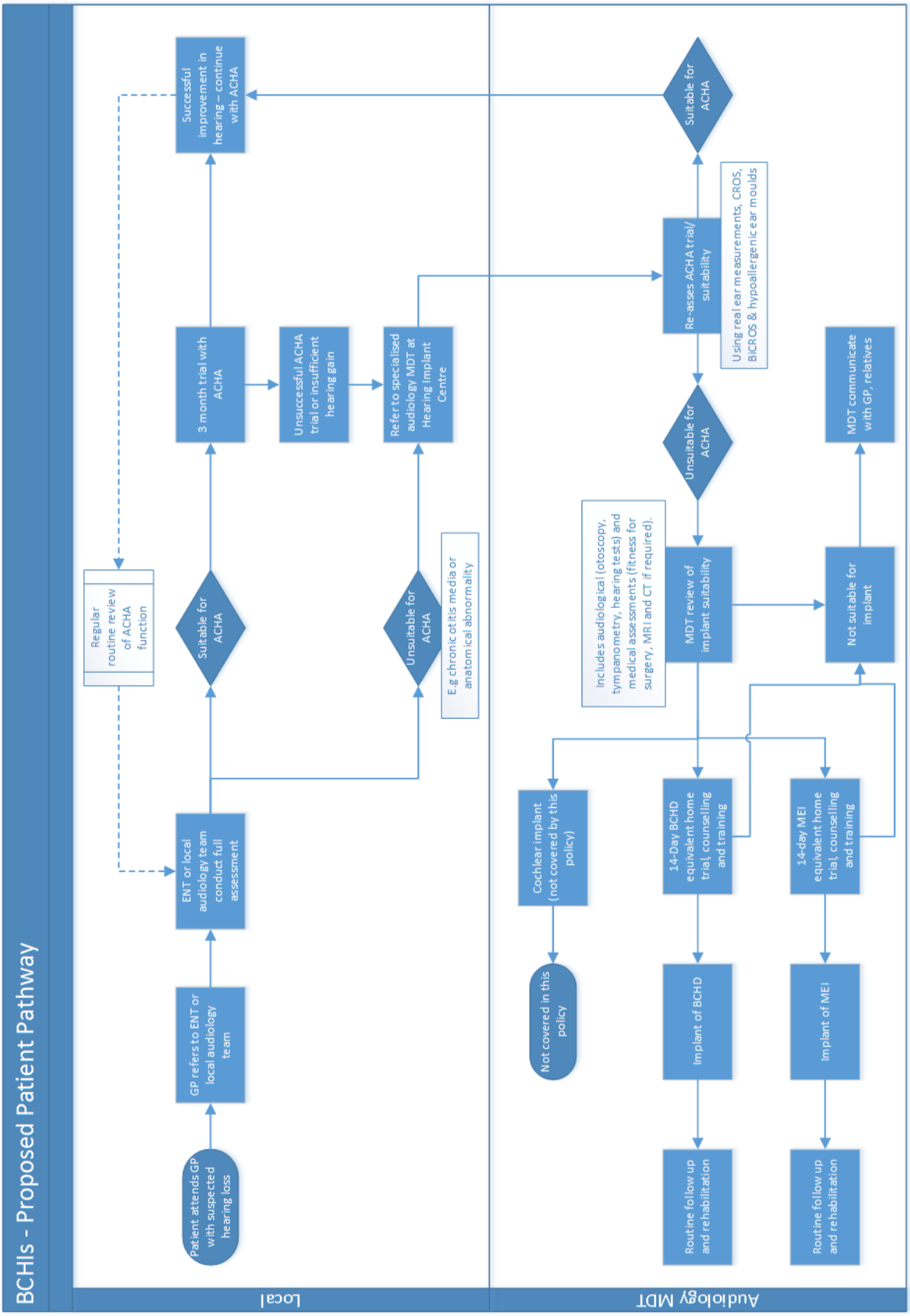
• Advice to other organisations e.g. trouble shooting advice to local staff (for children).

• Routine and regular reporting to local key workers (e.g. Teachers of the Deaf, Speech therapists) about progress and offering support with implant technology in the local setting.

• On-going support and maintenance – including a comprehensive spares and repairs service.

• Access to the implant medical / surgical / specialist nursing team as required.

• Records and measurements of the implanted device including software updates and test performed will be regularly taken.


BCHIs - Proposed Patient Pathway
Local
Audiology MDT
Patient attends GP with suspected hearing loss
GP refers to ENT or local audiology team
ENT or local audiology team conduct full assessment
Regular routine review of ACHA function
Suitable for ACHA
3 month trial with ACHA
Successful improvement in hearing – continue with ACHA
Unsuccessful ACHA trial or insufficient hearing gain
Unsuitable for ACHA
E.g chronic otitis media or anatomical abnormality
Refer to specialised audiology MDT at Hearing Implant Centre
Suitable for ACHA
Re-asses ACHA trial/ suitability
Using real ear measurements, CROS, BiCROS & hypoallergenic ear moulds
Unsuitable for ACHA
MDT review of implant suitability
Includes audiological (otoscopy, tympanometry, hearing tests) and medical assessments (fitness for surgery, MRI and CT if required).
Cochlear implant (not covered by this policy)
Not covered in this policy
14-Day BCHD equivalent home trial, counselling and training
Implant of BCHD
Routine follow up and rehabilitation
14-day MEI equivalent home trial, counselling and training
Implant of MEI
Routine follow up and rehabilitation
Not suitable for implant
MDT communicate with GP, relatives

9. Proposed governance arrangements

Hearing implant centres must be able to provide full audiological care for patients undergoing assessment, and implanted patients requiring long-term follow-up. Therefore, hearing implant centres assessing for BCHD and MEI must offer hearing aid reassessments, contralateral hearing aid fittings, CROS/BiCROS fittings, BCHD and MEI programmes to effectively assess and rehabilitate patients with the most appropriate devices prior to implantation. As the assessment and rehabilitation required to support successful use of hearing implants can be highly complex, these services will be provided by either a hearing implant centre or on an outreach/shared care basis where appropriate.

Hearing implant centres must be able to offer all types of hearing implants (excluding brain stem implants) or must be part of an agreed network with a unit that does offer all hearing implants so as to ensure patients can be fitted with the most appropriate device for their hearing loss, as decided by MDT.

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

Quality Standards:

The most recent “Quality standards for bone conduction implants” was produced by a multi national consensus in 2015. (Gavilan, Adunka et al. 2015)

Where elements of the hearing 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.

The service will have appropriate policies which cover, as a minimum

• Device failure

• Lost devices

• FM policy and Assistive Devices

• Upgrade of Devices

• 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.

10. Proposed mechanism for funding

NHS England will be responsible for funding the service, in line with this policy, on behalf of the population of England.

11. Proposed audit requirements

There is currently no recognised national database. The service specification records relevant outcome measures. Service providers will be expected to collect and provide audit data on request.

12. Documents which have informed this policy proposition

NHSCB D09/P/a, Clinical Commissioning Policy: Bone Anchored Hearing Aids, April 2013.

NHSCB D09/Ps/a, Clinical Commissioning Policy Statement: Active Middle Ear Implants, April 2013.

13. Date of review

This document will lapse upon publication by NHS England of a clinical commissioning policy for the proposed intervention that confirms whether it is routinely or non-routinely commissioned (expected by June 2016).