Appendix One – Stakeholder/CRG Feedback

Auditory Brainstem Implant – Service Specification

Organisation Responding	Feedback Received	PWG response	Resulting Action
Medway Maritime Hospital	No proposed changes to the document.	Noted	None required
Cochlear Europe Ltd	As a representative of a manufacturer of the auditory brainstem implant (ABI) we have comments over two statements and one broad topic in the document that need clarification. 1. Under "Device selection" (page 4), 2nd bullet point states "Have CE approval" as a requirement of the device. To Cochlear's knowledge, no ABI device currently offered on the market for sale has CE-mark for the indication group specified in this document. In Cochlear's case the ABI is approved and does have CE-mark for a different indication (neurofibromatosis type 2, cochlear nerve avulsion and total cochlear ossification) and age group (age 12 years and above). Obviously if any manufacturer should obtain CE approval for paediatrics (below 12 years of age) then they must surely be considered preferably, but if our current knowledge of approval is true, no manufacturer is able to provide a "CE approved" device and hence this service could not be considered. It is proposed	The PWG acknowledged this point and recognise that the devices are not currently licenced for use in children under 12 years of age.	Specific reference to "CE approved" has been removed. Safety of device selection will be assured by the remaining requirements stated under "device selection".

	that the document be re-worded to specify that the manufacturer must have CE-mark for some indication (not necessarily this indication) and that if approval is obtained by a manufacturer for this indication they would become the device of choice.		
	2. Under "Post-Operative care" (page 4), 5th bullet point states "written manufacturers safety guidelines". Subject to point (1) above being correct for all device manufacturers, then any safety guidelines provided by the manufacturer will NOT be for the indication specified in this document. Indeed since the use in paediatrics (under 12 years of age) is specifically and currently "off label" from a CE-mark perspective, the manufacturer makes no warranty or claim, and is unable to make warranty or claim, about safety in this population.	The PWG acknowledged that current guidance is for children aged 12 and over, but the group felt that this was still relevant for children of all ages in the absence of specific guidelines for younger children.	The bullet point has been adjusted to read: "Written manufacturers safety guidelines as indicated for older children" to clarify this point.
	3. Subject to point (2) above, Cochlear's warranty is extended for 10 years against mechanical or electrical defect causing loss of clinical benefit (see also "Device Failure" (page 5). No other warranty is provided.	Noted.	
	The document would do well to make clear (certainly to the parents/carers during counselling) that reoperation of an ABI (either due to device failure or due to movement requiring replacement of the electrode array) may be precluded due to conditions encountered during surgery (e.g. excessive fibrosis preventing safe removal of the old electrode array and potentially hampering or preventing insertion of a new device).	The PWG agreed with this statement. Information regarding re-operation would be provided within the written service information available to parents.	Information to be included in service information available to parents (not the specification).

	Declared Conflict of Interest: Cochlear represents a commercial supplier of the ABI device. No part of this response nor agreeing to be a supplier for the listed indication (if chosen), should be interpreted as our endorsement for use of the ABI in an "off label" indication. If any ambiguity in language or intent is understood, please contact Cochlear for further clarification.	Noted.	
PAN London ABI Service for children with congenital abnormalities of the auditory nerves or cochleae	No proposed changes to the document.	Noted	None required
Changing Faces	The document doesn't mention the knowledge and awareness of disfigurement that is needed by healthcare professionals and psychologists when treating children who need ABI. ABI's have a disfiguring effect and disfigurements can have a significant emotional, psychological and social impact on children's' lives and their parents/carers'. Health professionals benefit from learning about its impact, assessments and responses to better meet the needs of their patients and their families. The extent or severity of a disfiguring condition does not correlate with the amount of distress it can cause[12] and health professionals	The PWG acknowledge the importance of this area, however, it was not considered that the insertion of an ABI in a child (for this specific indication) would result in disfigurement. Only a small scar behind the ear is visible post-surgery. The potential of complications including the	None required

[1] Rumsey, R., Harcourt, D. (2005). The Psychology of Appearance. Open University Press, Maidenhead.

	do not always have the confidence or skills to address disfigurement related concerns. Between Nov. 2016 and Feb. 2017 Changing Faces conducted research[3] amongst more than 800 respondents with disfigurements and asked them questions about all aspects of their lives, including health. 42% of respondents said that their disfigurement has a severe or very severe impact on their lives. Nearly 60% of respondents said that their healthcare professional had very little or no understanding at all of the psychosocial impact of their condition and a similar proportion reported that they don't respond, or have a poor response to their psychosocial needs.	risk of facial nerve damage would be discussed with parents whilst obtaining consent for the procedure. It is recognised that facial disfigurement may result in adults receiving an ABI following NF2 surgery, however, the disfigurement is likely to result from removal of the tumour, rather than insertion of the ABI.	None required
	We believe that inclusion of understanding and awareness of the psychological aspects of disfigurement – and the need for training - would improve this specification.	The specification already includes Paediatric Clinical Psychologist (with experience of working with hearing impaired children and/or complex needs) as part of the wider MDT.	None required

[2] Moss, T.P. (2005). The relationship between objective and subjective ratings of disfigurement severity and psychological adjustment. Body Image 2,2, p151-159.
[3] Disfigurement in the UK, Changing Faces, May 2017,

Children with Auditory Brainstem Implants	**Care Pathway** - there are a small number of post-lingually deafened children over the age of 5 for whom a CI is not an option (cochlea ossification/damage from illness/trauma). These children should also be eligible for assessment.	In line with the agreed Clinical Policy this service is only for children with congenital abnormalities of the auditory nerves or cochleae. The group felt that cases referred to in the comment would be exceptional and therefore suitability of surgery would need to be addressed as an Individual Funding Request (IFR), and would be managed outside of the specification.	None required
	Rehabilitation - due to size of patient population it may be difficult to find "experienced" practitioners so collaboration with other ABI centres both nationally and internationally will be key to developing this specialism. It is not sufficient to simply adopt the same techniques as with a CI. The learning trajectory for ABI's is a lot longer and listening potential is often not reached until year five post activation.	The highly specialised nature of this service is recognised. All HSS services are required to formally collaborate nationally / internationally, and be subject to peer review. The requirement for collaboration is already included within the service specification, as	None required

		is access to an second opinion within England.	None required
	Whilst speech perception measures should and must be performed at regular intervals, practitioners should not compare the speech development of ABI children to CI children - it causes a great deal of distress to the child and their family. Sensitivity is required when communicating the results of such testing to the family.	The group agreed with this point is already reflected in specification under rehabilitation.	
	Device Failure - re-implantation may not always be possible due to the scar tissue and placement of the electrodes/damage when removing. Perhaps this should be worded as "where possible".	Noted.	Wording revised: "where possible" has been included
Royal College of Physicians	The RCP is grateful for the opportunity to respond to the above consultation. We have liaised with the British Association of Audiovestibular Physicians and would wholeheartedly endorse the consultation document.	Noted	None required