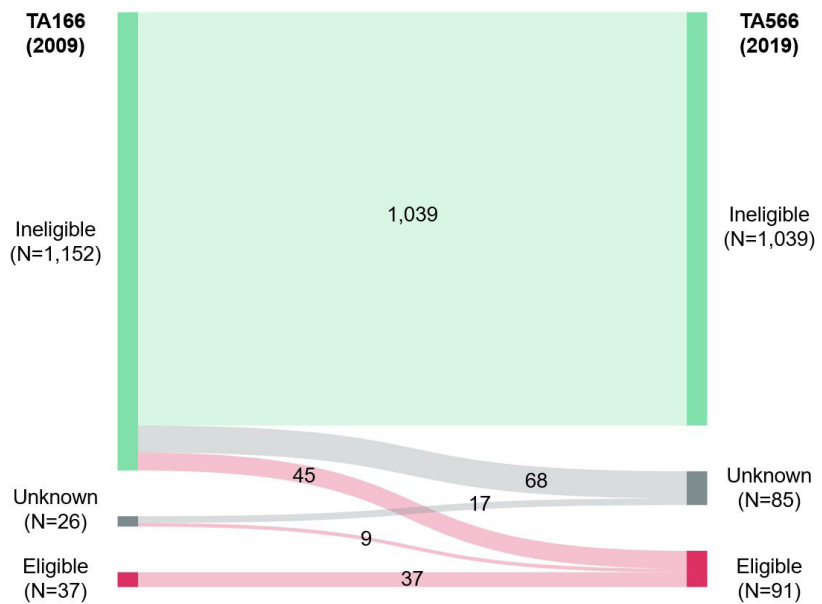


# Impact of NICE technology appraisal guidance TA566 on access to cochlear implantation for children using hearing aids in the United Kingdom: a multisite observational study

Early intervention is essential for deaf and hard-of-hearing children’s oral/aural language development. For sensorineural hearing loss, devices include acoustic hearing aids (HAs) and cochlear implants (CIs). Access to CIs in the UK is subject to technology appraisal (TA). The TA audiometric criterion defines which children are referred from HA to CI services for candidacy assessment and influences candidacy. TA166 required unaided air-conduction hearing threshold levels (HTLs) of  $\geq 90$  dB HL at 2 kHz and 4 kHz bilaterally.<sup>1</sup> TA566 expanded this to at least two HTLs of  $\geq 80$  dB HL bilaterally, including 0.5, 1, 2, 3 and 4 kHz.<sup>2</sup>

We assessed how TA566 changed children’s eligibility for CI referral using four hospitals’ paediatric HA caseloads (Bradford, Huddersfield, Calderdale and Nottingham). Non-identifiable routine audiology data were collected during 2019–2021. Included cases were <18 years old and prescribed at least one HA but no CI. Bone conduction aid (BCA) users were excluded as BCA and CI indications did not overlap. Whole caseloads were screened to avoid selection bias. Ascertainment was reported to be 100%, although this could not be verified. Device(s) prescribed and behavioural or electrophysiological HTLs (bilateral ear-specific or binaural soundfield) were extracted. Children were classified as falling within, outside or being unclassifiable by TA166<sup>1</sup> and TA566.<sup>2</sup> Numbers of children not eligible, newly eligible, of unknown eligibility and



**Figure 1** Sankey diagram of the impact of TAG566 on children’s audiometric eligibility for cochlear implantation. For both the 2009 (left axis, National Institute for Health and Care Excellence Technology Appraisal Guidance 166) and 2019 (right axis, National Institute for Health and Care Excellence Technology Appraisal Guidance 566) guidance. Children whose unaided hearing thresholds from the two most-recent audiograms made them audiometrically ineligible, of unknown eligibility, or eligible are represented by green, grey and red vertical bars respectively. The numbers in the centre of the figure describe the number of children whose status did or did not change from and to each category. TA, technology appraisal.

previously eligible for CI referral were derived and the percentage of HTLs measured at each frequency were calculated for each group.

Figure 1 shows changes in audiometric eligibility.

Figure 2 shows the percentage of cases for which HTLs at each frequency were available, by audiometric eligibility group. Data are for right ears where ear-specific HTLs were available and binaural soundfield thresholds otherwise.


TA566 expanded the proportion of children audiometrically eligible for CI referral from 3.0% to 7.5%. However, the rate of new child CI recipients UK-wide, which had been rising, plateaued following TA566’s implementation in June 2019 then fell and stabilised below prepandemic levels.<sup>3</sup> Research is needed to determine whether this was due to reduced incidence or detection of hearing loss, fewer referrals offered, parents declining referrals, referred children not being offered CIs or other causes.

TA566 eligibility group	Percentage of HTLs measured					
	Frequency (kHz)					
	0.25	0.5	1	2	3	4
Not eligible (N = 1,039)	78	99	99	99	24	99
Eligibility unknown (N = 85)	28	70	79	49	1	79
Newly eligible (N = 54)	78	94	98	91	50	93
Previously eligible (N = 37)	89	92	95	97	51	97

**Figure 2** Heat map of proportion of unaided hearing thresholds recorded on the two most-recent audiograms for each audiometric frequency by TA566 eligibility group. HTL, hearing threshold level; TA, technology appraisal.

TA566 increased the proportion of children whose audiometric eligibility for CI referral was unknown, from 2.1% to 7.0%. This was due to missing HTLs across frequencies, most markedly at 3 kHz. Full audiograms should be measured where this influences management. To promote equitable access to CIs for children less able to supply full audiograms due to, for example, age or developmental delay, research could establish referral and/or candidacy guidance requiring fewer HTLs.

The caseloads sampled may not have been representative of all children using HAS in the UK. Conductive overlays and non-audiometric candidacy criteria assessed by CI services, including language development and fitness for surgery, could not be considered. Teenagers <18 years old on adult caseloads were not captured. Nonetheless, this study provides a benchmark against which HA and CI services can compare referral rates and will inform future audiology practice and referral guidance.

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**Acknowledgements** The authors acknowledge the support of the research and innovation teams at each participating hospital and at the Nottingham Biomedical Research Centre (Hearing Theme).

**Contributors** PTK, CFK, DJH and DEHH conceived the work. RG, KW, NW, SM, PC and LG facilitated and informed data extraction. CFK, PC, FI, SN and JC extracted, pseudonymised and shared data. CFK performed statistical analyses and drafted the manuscript. RG, KW, NW, SM, LG, FI and JC contributed stakeholder feedback on the interpretation of data as practising audiologists. All authors reviewed the final version.

**Funding** This work was part of a PhD funded by the UK's National Institute for Health and Care Research via the Nottingham Biomedical Research Centre (Hearing Theme) and Cochlear Corporation.

**Competing interests** Since the initial planning of the work: Salary support for PTK, DJH and DEHH and CK's stipend were provided via a National Institute for Health and Care Research (NIHR) infrastructure award to their institution (NIHR Nottingham Biomedical Research Centre). CK's student stipend was supplemented by Cochlear Europe Ltd. During the past 36 months: NIHR Nottingham Biomedical Research Centre received an investigator-initiated grant from Cochlear Ltd to conduct an independent randomised controlled trial related to adult CI candidacy (PTK, CK, DEHH) and grants and contracts from Innovate UK and Rinri Therapeutics (DEHH). DEHH has an otology-related patent pending. DEHH received consulting fees from Bionics Institute, Melbourne, Australia and Rinri Therapeutics. DEHH received support for attending meetings and/or travel from Advanced Bionics, Rinri Therapeutics, and Cochlear Ltd. DEHH has participated on a data safety monitoring board or advisory board for Bionics Institute, Melbourne, Australia. Equipment has been donated to the University of Nottingham by Advanced Bionics (DEHH). DEHH is employed as Chief Medical Officer for and has stock or stock options in Rinri Therapeutics. Article processing charges provided by NIHR infrastructure award. DJH has been Chair and Immediate Past Chair of the British Society of Audiology, and CK an Ordinary Member of the board of trustees of the British Cochlear Implant Group. None declared for RG, NW, SN, LG, FI, JC, KW, SM, PC.

**Patient consent for publication** Not applicable.

**Ethics approval** This study involves human participants and was approved by Nottingham 2 Research Ethics Committee (reference: 19/EM/0302). With the approval of the ethics committee, consent

for participation was not required. This reflected the importance of including data from whole caseloads of children to avoid bias, and the method used that was deemed to preserve the anonymity of participants.

**Provenance and peer review** Not commissioned; externally peer-reviewed.



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**To cite** Killan CF, Hoare DJ, Hartley DEH, *et al*. *Arch Dis Child* 2024;**109**:690–691.

Accepted 18 April 2024  
Published Online First 23 May 2024

*Arch Dis Child* 2024;**109**:690–691.  
doi:10.1136/archdischild-2023-326055

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