Technology Guidance

Cochlear Implants

for children with single-sided deafness

Technology Guidance from the MOH Medical Technology Advisory Committee

Guidance Recommendations

The Ministry of Health's Medical Technology Advisory Committee has not recommended cochlear implants for children with single-sided deafness.

Funding status

Cochlear implants are not recommended for subsidy in patients with the abovementioned indication.

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Factors considered to inform the recommendations

Technology evaluation

1.1. The MOH Medical Technology Advisory Committee ("the Committee") considered the evidence presented for the technology evaluation of cochlear implants (CIs) for children (<18 years) with single-sided deafness (SSD). The Agency for Care Effectiveness (ACE) conducted the evaluation in consultation with clinical experts from public healthcare institutions (PHIs). Published clinical and economic evidence for CI was considered in line with its registered indication.

1.2. The evidence was used to inform the Committee's deliberations around five core decision-making criteria:

- Clinical need of patients and nature of the condition;
- Overall benefit of the technology for the patient and/or the system;
- Cost-effectiveness (value for money), which considers the incremental benefit and cost of the technology compared to existing alternatives;
- Estimated annual technology cost and the number of patients likely to benefit from the technology; and
- Organisational feasibility, which covers the potential impact of adopting the technology, especially barriers for diffusion.

1.3. Additional factors, including social and value judgments, may also inform the Committee's deliberations.

Clinical need

2.1. SSD is defined as severe-to-profound hearing loss of more than 61 decibels (dB) in one ear, with near normal or normal hearing in the other ear. In children, SSD may be acquired or result from congenital anomalies of the inner ear, hypoplastic or aplastic cochlear nerves or congenital infections. The local incidence and prevalence of SSD in children are not well captured. A 2022 US study estimated SSD prevalence as 0.36% in a cohort of children undergoing audiometry.

2.2. Children with SSD have impaired ability to distinguish sound direction (sound localisation) or perceive speech in noisy environments. They may also have poorer speech and language development and lower overall quality of life (QoL), compared with children of a similar age without SSD. Initial management for SSD in children involves conservative management with contralateral routing of signals (CROS) hearing aids or no treatment. Bone conduction hearing implants (BCHIs) or wearable bone conduction devices (BCDs) may also be an option. CI may be considered in children with SSD in whom conservative management has not been successful or if BCHIs and wearable BCDs are contraindicated..

2.3. Currently, BCHIs and wearable BCDs are subsidised for children with SSD. Both treatments are likely to provide improvement in terms of functional gain, hearing-specific QoL and patient satisfaction, However, BCHIs and wearable BCDs do not restore binaural hearing and prolonged lack of stimulation in the deaf ear may affect brain development.

2.4. The CI system consists of an external component (sound processor, transmitter) sitting behind the ear and internal component (receiver, electrode) implanted under the skin and within the cochlear, respectively. Sound is captured and converted to a digital signal by the sound processor and sent via the transmitter to the receiver. The receiver converts the digital signal into electrical energy to stimulate the cochlear nerve. The brain then interprets the stimulations as sound. Due to its mechanism of action, the CI system is contraindicated in those with cochlear nerve deficiency. It is hypothesised that CI can restore binaural hearing by directly stimulating the non-hearing ear. CI may be more effective to reverse abnormal cortical organisation from SSD in children under four years given higher neuroplasticity at younger ages. In patients with prolonged hearing deprivation or a cochlear nerve deficiency, a BCHI or wearable BCD is preferred.

Overall benefit of technology

3.1. The Committee acknowledged that the appropriate comparators for CI were BCHIs or wearable BCDs, and no treatment. The evidence base comprised two health technology assessment (HTA) reports, two systematic reviews (SR) and one additional primary study.

3.2. The Committee noted that CI for children with SSD is reasonably safe based on evidence of their use in patients with bilateral deafness which showed major complication rates of 3.2% to 5%. Revision rates due to device failure, infection, or trauma ranged from 5% to 10.2%.

3.3. The Committee noted that naïve comparisons of CI with BCHI or wearable BCD showed similar improvement in pre-post assessments of speech perception in quiet and noise at six-month follow-up, and hearing-specific QoL at 12-month follow-up. However, the lack of head-to-head studies comparing CI with BCHIs or wearable BCDs made it difficult to determine their comparative effectiveness in children with SSD. Compared to no treatment, CI improved speech perception in quiet and noise, sound localisation, speech and language development and hearing QoL at 12-month follow-up.

3.4. The Committee noted the overall clinical evidence base was of very low quality due to lack of direct comparisons of CI with the comparators, inadequate statistical correction for pre-post data, heterogeneity in outcome measurements and

instruments used, and incomplete reporting.

Cost effectiveness

4.1. The Committee noted that no study was identified that compared CI with BCHI or wearable BCD for children with SSD.

4.2. One cost-utility analysis (CUA) from the HTA report found that compared to no treatment, CI in children with SSD yielded an incremental cost-effectiveness ratio (ICER) of SGD$18K per quality-adjusted life year (QALY) gained over a time horizon of 25 years. The Committee acknowledged that this finding was highly uncertain as utility inputs in the CUA were based on a small case series of 11 adults which was assumed to be the same in children. The report identified that the key drivers of ICER were health utility associated with CI use, and probability of non-use of CI. Sensitivity analyses that varied the time horizon or health utility values od CI use yielded ICERs ranging from SGD$11K to SGD$54K per QALY.

4.3. Given the lack of comparative evidence and current prices for CIs in Singapore, the Committee concluded that it was unlikely that CIs for children with SSD would be cost-effective.

4.4. Currently, CIs for the management of SSD in children are not reimbursed for SSD in children in Belgium, South Korea, New Zealand, Taiwan, France and the UK. Local clinicians shared that while CIs are reimbursed in Australia, caps may be imposed on the total number of procedures across different states.

Estimated annual technology cost

5.1. The Committee noted that the annual cost impact to the public healthcare system was estimated to be <SG$1 million, based on the projection of 18 children with SSD in Singapore who would benefit from Government subsidy for the CI system.

Organisational feasibility

6.1. The Committee noted that no organisational feasibility issues were identified.

Additional considerations

7.1. The Committee noted that the clinical need for CI for children with SSD appeared to be low, based on historical utilisation data for CI and BCHI and wearable BCDs utilisation of five patients across all public health institutions in Singapore from April 2017 to November 2022.

7.2. The Committee noted that there are seven interventional studies evaluating the effect of CI for children with SSD. One has completed and six are ongoing with expected completion dates up till 2030. The Committee noted that studies are often limited by small sample sizes arising from the rarity of the condition, as well as barriers including cost or reluctance to undergo surgery.

Recommendations

8.1. Based on available evidence, the Committee did not recommend listing CIs on the Implant Subsidy List (ISL) for children with SSD, given the limited clinical evidence, low local clinical need, availability of non-inferior subsidised alternatives such as BCHIs and wearable BCDs, and lack of reimbursement in most reference jurisdictions.