



Independent Clinical Review for the Paediatric Cochlear Implant Program – Summary for the Women’s and Children’s Hospital

May 2024

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1. Background

On 31 May 2022, Women's and Children's Health Network (WCHN) Paediatric Cochlear Implant Program initiated an internal review with respect to mapping for a cohort of patients who had received cochlear implants. This prompted the South Australian (SA) government to initiate an independent External Governance Review.

That External Governance Review formally commenced on 1 May 2023, and the final report was delivered on 9 August 2023 (South Australia Department for Health and Wellbeing, 2023). A total of 59 recommendations were accepted for implementation.

Further, WCHN undertook a "Look Back" process and identified 208 patients that had been involved in the Cochlear Implant program since 2006; 156 patients still considered to be a paediatric cohort were offered an independent clinical assessment.

Following this identification, in the middle of 2023, NextSense was approached by WCHN on behalf of the South Australian (SA) Government to provide an independent clinical review for the patients and families who received a cochlear implant (CI) and related services at the Women's and Children's Hospital (WCHN) Paediatric Cochlear Implant Program in Adelaide between 2006 and 2023. A total of 107 patients/families elected to participate in the Clinical review conducted by NextSense.

2. Purpose and Scope

The purpose of the NextSense Independent Clinical Review was to assess the patient's access to sound through their cochlear implant and their current communication skills, as well as reviewing their hospital file for audiological and medical history, and other factors that may contribute to the patient's outcome.

From 31 July 2023 to 23 January 2024, NextSense clinically reviewed 107 patients who elected to be involved (169 individual reviews were conducted, accounting for patients who have 2 cochlear implants). At the time of review, the age range of

patients involved was between 1 year, 5 months and 20 years, 11 months. Of these patients 47% had documented additional needs such as Autism Spectrum Disorder (ASD), Attention Deficit Hyperactivity Disorder (ADHD) and Global Developmental Delay. All patients participated in an audiology assessment and file review. Of the patients involved in the review, 47 received a speech and language assessment with NextSense.

The review process included:

- A file review of each patient who fell within the scope of the clinical review.
 - The purpose of this was to undertake a review against WCHN Cochlear Implant Program Audiology Protocols and to understand the cochlear implant audiology services that had been provided to the patients compared with best practice standards.
- An in-person clinical review appointment conducted by a NextSense audiologist and a NextSense speech pathologist as appropriate for the patient's age and stage of development.
- Offering a Speech and Language Assessment if one had not been conducted in the past 12 months or incorporating an assessment report from the patient's therapy provider provided by the parent/carer for the purposes of the review.

The file review and in-person assessments began on 31 July 2023 and formally concluded on 22 December 2023 with one follow-up appointment occurring on 23 January 2024.

Individual patient review reports were provided to the WCHN at the conclusion of the case reviews. At the request of WCHN, as the Independent Clinical Review finalised, NextSense also participated in a number of family meetings to report on the findings of the clinical and file note review for individual patients. These were performed either in person or via teleconference. At the time of submitting this report, NextSense had supported 40 family review meetings.

A detailed "Independent Clinical Review for the Paediatric Cochlear Implant Program – Technical Report for the Women's and Children's Hospital" (April, 2024) was provided to

WCHN. Subsequently this Summary was provided. The Technical Report provided detailed findings and recommendations relating to six key elements of file and clinical review, including:

- Candidacy assessment (assessing patient suitability for a cochlear implant)
- Initial stimulation/acute mapping and ongoing mapping
- Verification of mapping
- Ongoing patient assessment and monitoring
- Program of supports (for example early intervention and rehabilitation) and coordination of care including with external providers
- Clinical review (in person)

A summary of these findings and recommendations are set out below.

3. Key Findings

In considering the six key areas above, 31 indicators have been used to summarise what percentage of the time key activities were evident or documented as having been carried out in the WCHN paediatric cochlear implant program, to align with international evidence-based practices and recommendations in the field.

Candidacy Assessment

Context: Assessing a person’s candidacy for cochlear implantation is an important part of the CI process. In addition to determining whether the candidacy criteria are met, it establishes a baseline for potential ‘candidates’ on which subsequent and ongoing care and service delivery is based. This ongoing care and service delivery relates to audiological management, speech, language and communication development and coordinated care around the patient including with external providers.

The percentage of time indicators for Candidacy Assessment were evident or documented as having been carried out can be seen in the table below.

Percentage of time indicators were evident	Percentage of cases
Less than 50%	50%
50-64%	0%

65-74%	0%
75-84%	37.5%
85-100%	12.5%

Table 1 Candidacy Assessment. Number of indicators: 8

Initial Stimulation

Context: Following cochlear implant surgery, there are a number of key services that are delivered to a CI recipient. Initial stimulation typically occurs 2-3 weeks after surgery and is when the cochlear implant is activated for the first time.

The percentage of time indicators for Initial Stimulation were evident or documented as having been carried out can be seen in the table below.

Percentage of time indicators were evident	Percentage of cases
Less than 50%	0%
50-64%	0%
65-74%	0%
75-84%	25%
85-100%	75%

Table 2 Initial Stimulation. Number of indicators: 4

Acute Mapping and Ongoing Coordinated Care

Context: Acute and ongoing mapping involves programming the cochlear implant to provide access across the speech frequencies, from low to high pitch sounds. This is performed over a number of appointments and using a range of specific measures so access to sound, audibility, and progress can be monitored.

Ongoing, holistic care involves a range of factors including continued mapping/programming of the cochlear implant and verification of the programs provided, therapy supports, consistent monitoring and tracking of listening and communication skills and feedback among team members both internal and external to WCHN, within the ecosystem of care.

The percentage of time indicators for Acute Mapping and Ongoing Coordinated Care that were evident or documented as having been carried out can be seen in the table below.

Percentage of time indicators were evident	Percentage of cases
Less than 50%	58%
50-64%	5%
65-74%	11%
75-84%	16%
85-100%	11%

Table 3 Acute Mapping and Ongoing Coordinated Care. Number of indicators: 19

Summary of indicators

An overall summary for the 31 indicators above can be found in table 4 below.

Percentage of time indicators were evident	Percentage of cases
Less than 50%	48%
50-64%	3%
65-74%	6%
75-84%	23%
85-100%	19%

Table 4 Overall summary. Number of indicators: 31

Overall findings suggest several factors that may have impacted on the ability for WCHN to demonstrate efficacy of their patient management following cochlear implantation, track expected progress and identify and act upon areas of concern early to maximise outcomes.

Key areas in the clinical care management and pathway for patients before and after cochlear implantation require further development to align with current international evidence-based practices and recommendations in the field.

Specifically, these include:

- comprehensive clinical protocols and guidelines which include a range of pre- and postoperative audiological assessment measures for different populations;
- outcomes collection and tracking as well as quality assurance measures and continuous improvement approaches;
- staff development and support; and
- delivery of coordinated care across service providers and disciplines.

A trend of limited mutual communication or collaboration between key internal and external providers engaged in the patient's care was noted. The model of care as an audiology and surgical-only service requires effective collaboration between WCHN and external therapy providers to ensure coordinated care and outcomes for children within the cochlear implant services are monitored.

4. Recommendations

For the best outcomes, children receiving cochlear implants and their families need care from a range of professionals and it is imperative that care is evidence-based and coordinated effectively (Cullington et al., 2023).

Based on the findings of the Clinical Review, the following recommendations are provided:

1. Review current service models, clinical guidelines and protocols to align with contemporary evidence-based best practice standards.
2. Clearly define a scope of service that enables the delivery of coordinated multidisciplinary care with the patient and family at the centre, including ongoing review at specified intervals.
3. Develop and implement robust evidence-based processes and standardised written guidelines around clinical management of different clinical populations, and individual appointment activity, including:
 - (a) Age-and-skill-appropriate pre-operative and post-operative assessment
 - (b) Device programming guidelines
 - (c) Map optimisation and validation guidelines
 - (d) Review and implementation of WCHN recommended appointment schedule for candidacy, acute management and ongoing care
 - (e) Development and implementation of a clinical 'at risk' escalation process
4. Review of resourcing and equipment to allow for appropriate management and assessment of patients depending on age, ability and presentation. Plus, the provision

of coordinated internal and external multidisciplinary care which includes (in the context of the current service model):

- (a) Regularly scheduled team meetings to discuss and manage care and any ongoing issues regarding progress and outcomes.
- (b) Ensuring appropriate programs of support are in place around the patient and family before and after cochlear implantation.
- (c) Establishing links with external providers for early intervention/therapy provision, ensuring records are shared appropriately and communication is consistent between audiologist and the therapy provider to optimise the patient's outcome for audition, speech, language and communication development, and to further support developmental needs.

5. Embed quality improvement processes and monitoring of clinical standards of practice such as adherence to protocols in addition to continuous review of protocols against emerging research evidence.

6. Embed defined outcomes measurement and reporting, supported by a robust clinical and data management process to capture patient outcomes data to assist in monitoring progress and outcomes and support future research endeavours.

7. Develop clinical competency frameworks that align with clinical protocols and guidelines in addition to ongoing staff training, and clinical supervision including professional development as well as mentoring and supervision that is aligned with recommendations from professional bodies.

Implementing these recommendations will assist in streamlining service delivery and support effective delivery of evidence-based and coordinated clinical care. This will also enhance the ability to identify and address areas of clinical concern at an early stage, thus continuing to maximise clinical progress and optimise patient outcomes.

5. Conclusion

Over the course of 5 months in 2023, NextSense reviewed 107 patients (169 individual reviews were conducted, accounting for patients who have 2 cochlear implants). All patients participated in an audiology assessment and file review. Of the patients involved in the review, 47 received a speech and language assessment with NextSense.

Overall, the findings of the NextSense Independent Clinical Review highlighted a number of areas for development, including the need to provide children receiving a cochlear implant with a coordinated care approach to create a best practice ecosystem across all services and disciplines, to update and adhere to evidence-based protocols for audiology and (re)habilitation / therapy including appointment cadence, and to provide staff with continuous professional development and clinical supervision.

6. Appendix

List of 31 Indicators

Candidacy Assessment

Indicators: Candidacy Assessment	
1	Pre-CI hearing threshold levels in line with recommended WCHN protocol
2	Aided hearing outside the speech spectrum
3	Speech perception testing performed to verify candidacy
4	Functional listening questionnaire completed to inform candidacy
5	Baseline speech and language assessment completed/noted
6	Evidence of enrolment in early intervention / (re)habilitation program of support, pre-CI
7	Liaison with Hearing Australia evident
8	Liaison with AVT/ Teacher of the Deaf /Speech Pathologist evident

Initial Stimulation

Indicators: Initial Stimulation	
1	Initial Stimulation within 2-3 weeks after surgery
2	Evidence of Neural Response levels / objective intraoperative testing at surgery
3	Baseline Map set for ongoing Mapping, using objective testing / Neural Response profile and/or behavioural observation
4	Electrode impedance check performed to assess for open or short circuits

Acute Mapping and Ongoing Coordinated Care

Indicators: Acute Mapping and Ongoing Coordinated Care	
1	Number of mapping episodes from Initial Stimulation to 3 months post-CI *expected number 4-6
2	Number of mapping episodes within 3-6 months post-CI *expected number 1-2
3	Number of mapping episodes within 6-12 months post-CI *expected number 1-3
4	Number of mapping episodes within 12-24 months post-CI *expected number 2-4
5	Number of mapping episodes within 2-5 years post-CI *expected number 6-8

6	Electrode impedance check performed to assess for open or short circuits
7	Threshold levels measured on a sample of channels across array (Nucleus device only)
8	Loudness optimised through 'most comfortable level' measures (global and/or individual channel measures)
9	Loudness discomfort checked binaurally in live mode or with 'most comfortable level' sweeps?
10	Neural Response profile / objective measures used to set Maps following Initial Stimulation
11	Ling 6 Sound Test presented separate ears listening alone completed at every Map entry reviewed
12	Formal annual speech perception evaluation was reported in order to monitor any reduction in abilities
13	A formal speech and language assessment at 12 months post-CI (e.g., PLS or CELF) is on file. *expected number 1 report
14	Evidence of an early intervention / (re)habilitation program of support in place post-CI
15	Evidence of feedback to and from audiologist and therapists regarding progress in early intervention / (re)habilitation program of support.
16	Map levels 'stable' when compared with the NextSense review map at closest map to May 2022
17	Map levels 'stable' when compared with the NextSense review map at most recent map on file
18	Ling 6 Sounds pre-Map: - detection of all speech sounds.
19	Pre-Mapping CI Assisted Thresholds– detection at or better than 35dBHL at all frequencies?

Definitions

Term	Definition
Hearing threshold	The softest sound the child can hear at a particular frequency, measured in dBHL or dBSPL.
Speech perception	The process of recognising and interpreting / understanding speech when listening alone without visual cues. This can be sounds, words or sentences.
Communication assessment	Assessment of the child's communication skills.
Mapping	Programming of the child's cochlear implant device.
Threshold level	Also referred to as 'T' level: The softest sound the child can hear on a particular channel in their map.
Comfort level	Also referred to as 'C' level: The level at which the child finds the sound comfortably loud; the loudest level set for a particular channel in the child's map.
Channel	A channel of a cochlear implant corresponds to an allocated frequency (pitch) band.
Array	The cochlear implant electrode array.
Loudness optimisation	Making sure that sounds heard through the cochlear implant are approximately equivalent in loudness to the range of environmental sounds heard by those with typical hearing. Loud sounds should be loud but comfortable and soft-moderate sounds should be perceived as soft-moderate by the CI user.
Neural responses	Automatic measures where the child doesn't have to give a response. These measures show objectively that the child's hearing nerve is responding to sound.
Ling 6 sounds	The sounds used for the Ling 6 Sound Check are "ahh", "eee", "ooo", "mmm", "shh", and "sss". These sounds represent speech in the low, mid, and high frequencies are presented listening alone without visual cues.
Mapping levels	The threshold (softest sound the child can hear) and comfort levels (the most comfortably loud sound the child can hear).
CI assisted thresholds (CIATs)	The child's response to sounds in a testing environment in the sound booth.
Baseline map	The first map the child receives at initial stimulation.
Electrode impedance check	Check of the individual electrode functioning of the cochlear implant device.

7. References

Note that a full reference list is included in the Technical Report

Cullington, H. E., Jiang, D., Broomfield, S. J., Chung, M., Craddock, L. C., Driver, S., Edwards, D., Gallacher, J. M., Jones, L. L., Koleva, T., Martin, J., Meakin, H., Nash, R., Rocca, C., Schramm, D. R., Willmott, N. S., & Vanat, Z. H. (2023). Cochlear implant services for children, young people and adults. Quality standard. *Cochlear Implants International*, 24(sup1), S1-S13. <https://doi.org/10.1080/14670100.2023.2197344>

South Australia Department for Health and Wellbeing. (2023). *Independent Governance Review, Paediatric Cochlear Implant Program, Women's and Children's Health Network South Australia, Final report*. <https://www.sahealth.sa.gov.au/wps/wcm/connect/3ea94b77-d993-40ae-a3d1-90b55d7cba20/External+Governance+Review-PaediatricCochlearImplant-Review-FinalReport-9thAugust2023.pdf>