Independent Governance Review

Paediatric Cochlear Implant Program

Women's and Children's Health Network

South Australia

Final Report

9 August 2023

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ABBREVIATIONS

AudA	Audiology Australia
ACSQHC	Australian Commission on Safety and Quality in Health Care
AH	Allied Health
AHPs	Allied Health Professional
Ahpra	Australia Health Practitioner Regulation Agency
AIHW	Australian Institute of Health and Welfare
CaFHS	Child and Family Health Services
CC	Case Coordinator
CG CoP	Clinical Governance Community of Practice
CI/CIs	Cochlear Implant/Cochlear Implants
CPD	Continuous Professional Development
dB	Decibels
DHW	Department for Health and Wellbeing
DHH	Deaf and Hard of Hearing
EAP	Employee Assistance Program
EI	Early Intervention
ERT	External Review Team
ENT	Ear, nose, and throat
FMC	Flinders Medical Centre
HA	Hearing Aid
ISR	Incident Severity Rating
KPIs	Key Performance Indicators
LAH	Little Allied Health
LHN	Local Health Network

MDT	Multidisciplinary Team
NDIS	National Disability Insurance Scheme
NSQHS	National Safety and Quality Health Service
OD	Open Disclosure
PCHI	Permanent Childhood Hearing Impairment
RCH	Royal Children's Hospital
SA	South Australia
SACIC	South Australian Cochlear Implant Centre
SERC	Significant Events Review Committee
SLS	Safety Learning System
ToD	Teacher of the Deaf
ToR	Terms of Reference
UNHS	Universal Neonatal/Newborn Hearing Screening
WCH	Women's and Children's Hospital
WCHN	Women's and Children's Health Network

DEFINITION OF TERMS

This table explains audiology specific terms used in this report

3FAHL	Three frequency average hearing loss An average of the hearing thresholds for frequencies 500, 1000 and 2000Hz
Audiogram	Graphical representation of hearing thresholds for various frequencies as measured by an audiometer Typically assessed in an audiometric, soundproof test booth
Aided Audiogram	Graphical representation of hearing thresholds for various frequencies while wearing hearing aids or a cochlear implant
Aided thresholds	Indicates the softest sound an individual can hear when using a hearing aid or cochlear implant Typically assessed in an audiometric, soundproof test booth
Behavioural hearing test/testing	Test technique where child's response to sound is recorded. Requires the participant to be awake and demonstrate a physical/behavioural response to sound. Approach used will depend on the developmental age of the participant. Considered gold standard for measurement of hearing thresholds and defining hearing loss
dB (decibel)	A unit used to measure the intensity of a sound and represents the degree of loudness
dBSPL	A unit used to measure the intensity of a sound and quantified by sound pressure in air.
Electrophysiological hearing assessment	Method of determining hearing thresholds objectively Test monitors the activity of the brain and/or auditory nerve in response to sound stimulus
Functional assessment	Assessment of listening skills through informal observations and/or standardised tests These tests evaluate listening skills in different environments and can be compared to accepted norms to determine expected progress and skills have been developed
CAEP	Cortical auditory evoked potentials (CAEP) are used to evaluate access to auditory stimuli at the level of the cortex

	Can be used to assess the audibility of hearing aid amplified speech
FLI-P	The Functional Listening Index for Paediatric (FLI-P) is a functional tool for tracking and monitoring a child's listening skills in everyday situations
LittleEARS	LittleEARS is an auditory questionnaire of caregiver's observation used to assess and monitor the auditory development of children in everyday life
IT-MAIS	The Infant-Toddler Meaningful Auditory Integration Scale a (IT-MAIS) is a modification of the MAIS for application with infants and toddlers A functional assessment, administered as an interview, to assesses a child's spontaneous responses to sound in their everyday environment
kHz	Hertz (Hz) is the unit in which frequency or pitch of sound is measured 1kHz = 1000Hz
Ling sounds / Ling detection	A range of speech sounds encompassing the speech frequencies that are widely used clinically to verify the effectiveness of a hearing aid or cochlear implant fitting in children. Audibility of the Ling sounds should ensure audibility for all the sounds within the speech frequency range
MAIS	The Meaningful Auditory Integration Scale a (MAIS) is a functional assessment, administered as an interview, to assesses a child's spontaneous responses to sound in their everyday environment
Map	A customised program that determines how the electrodes in a recipient's cochlear implant will be stimulated May also be referred to as the cochlear implant program
Mapping	The process of measuring the amount of electrical current delivered to the cochlea by the implant. Achieved using custom software to program the cochlear implant to send electrical signals to the specific electrodes in the cochlea that correspond to the different frequencies of sound. May also be referred to as cochlear implant programming
MCL	Most comfortable level of electrical stimulation for given cochlear implant electrode
NAL-NAL2	Widely accepted prescription procedure/formula for the fitting of hearing aids
NRT	Measurement of the electrically evoked compound action potential in response to simulation from a cochlear implant

	Consistent with the hearing nerve firing in response to stimulation from the cochlear implant
PEACH	The Parents' Evaluation of Aural/Oral Performance of Children (PEACH) is a caregiver report questionnaire used to evaluate the effectiveness of a child's use of hearing in real-world environments
T and C levels	T level or threshold level is the softest electrical input level detectable by the cochlear implant recipient for each electrode C level or Upper-Stimulation level is the electrical input level that is perceived as loud, but comfortable to the cochlear implant recipient T and C levels are set during the mapping process
Speech perception	Involves measuring a person's ability to detect, recognise and understand spoken words and sentences Performance can be compared to the expected/average outcome with a cochlear implant

Disclaimer

Please note that, we are obliged to advise that none of the authors undertakes responsibility in any way whatsoever to any person or organisation (other than the South Australian Department for Health and Wellbeing) in respect of information set out in this report, including any errors or omissions therein, arising through negligence or otherwise however caused.

Dr Robyn Lawrence
Chief Executive
Department for Health and Wellbeing
South Australia
9 August 2023

Dear Dr Lawrence,

Thank you for inviting me to lead the panel to review the systems and processes that surrounded the mapping of paediatric cochlear implants at the Women's and Children's Health Network in South Australia. I am pleased to submit the report of the review on behalf of the review panel. The report contains an executive summary and the main report.

The ultimate outcome of this review is to ensure that the children of South Australia who are diagnosed with profound hearing loss and whose families choose to have a cochlear implant at the Women's and Children's Hospital as a mode of aided hearing have access to high-quality, comprehensive, and safe care. The panel has made some key recommendations after considering all the information available and believe that these are adopted to ensure that the probability that the identified mapping issues that have impacted the children and families, will never occur again.

The impact of a significant adverse event or complication during hospital care on a family member cannot be underestimated. The impact on the lives of families and loved ones is often profound and in some situations may be permanent. The families who have contributed to this review have lived experience of the devastation which follows such events and have discussed with the review team the critical importance of this review, with the hope that it will provide answers to their questions. Families have also expressed clearly that they want what happened to them to matter, and to ensure that sustainable change is put in place to ensure that voices, such as theirs, are heard and that what happened to them will not happen to other families in future.

The experiences of the families that received care at the Women's and Children's Health Network have implications not only for Paediatric Cochlear Implant Program there but for other paediatric Cochlear Implant services across Australia, that provide audiology services. Therefore, this report aims to not only address specific concerns related to the Paediatric Cochlear Implant Program at Women's and Children's Health Network, but also provide recommendations that may be applicable to all audiology service providers nationally.

External reviews of clinical services can be associated with a level of apprehension to frontline staff that are often doing their very best in what are often challenging circumstances. We thank the staff at the Women's and Children's Health Network for their openness and willingness to contribute to this review. As a multi-professional panel (ERT), each with a clinical background, we acknowledge this and believe that the recommendations in this report will ultimately lead to significant improvements in patient care and enhance safety.

Healthcare is inherently complex which is why health services must have robust clinical governance processes in place to minimise the risk of harm to our patients and families. Errors will and do occur, and when they do it is imperative that there are systems in place, to identify, report and review them, so that contributing underlying issues are addressed to prevent recurrence. It is rare that adverse clinical events occur in isolation or due to the actions of a single individual. More commonly, there is a system failure that has allowed a set of circumstances to develop that leads to the incident occurring.

To develop the recommendations, this review has examined all the information provided by the Women's and Children's Health Network, the Department for Health and Wellbeing, external stakeholders and importantly listened and talked to parents and carer about their experiences.

Regards

Amanda Singleton

Amanda Singleton
Lead Reviewer
Independent Governance Review

1. Executive Summary

1.1 BACKGROUND

On 31 May 2022, an external provider of audiology services in South Australia (SA) raised concerns regarding a potential issue with the mapping of Cochlear Implants (CI) at the Women's and Children's Health Network (WCHN). Concerns were raised initially in relation to four children who had transferred their audiology care from the South Australian Paediatric Cochlear Implant Program at the WCHN to the external provider.

An internal investigation was commenced at the WCHN that included a case note review for each of the children involved. A meeting was held with the external provider to understand the concerns in more detail. The concerns primarily related to potential under mapping of the CI and suggested that children may have had inadequate hearing for a significant period and that this may have impacted on their development. A fifth child was subsequently identified with similar issues, thus reaching the criteria to be defined as a cluster incident and this was documented in August 2022. Leadership of the external provider had raised their concerns not only with the WCHN but also with the Ministers Office in the Department of Health and Wellbeing (DHW).

The Chief Executive Officer (CEO) of the WCHN was notified of the cluster incident once this had been confirmed by the Allied Health Executive Lead. In August 2022, the CEO alerted the Board Chair of a potential issue with the Paediatric CI Program, but no formal documentation was provided as the extent of the issue was unknown at that time. Prior to the notification of the cluster incident, the WCHN executive were unaware of any operational issues within its Paediatric CI Program.

Following an initial internal investigation using lookback methodology, it became apparent that the mapping issues may have impacted significantly more children than originally thought and had potentially been going on over a long time. The WCHN team indicated that it had taken several immediate steps following identification of the issues to mitigate some of the concerns. However, despite this, there continued to be a level of agitation in relation to the Paediatric CI Program, and coupled with some adverse media publicity, the Minister for Health and Wellbeing announced there would be an Independent External Governance Review of the Paediatric CI Program at the WCHN. This announcement was made on 20 March 2023. Maintaining a focus on transparency, and as part of the external governance review, the Minister also announced that he was keen to hear from families of affected children in relation to their experiences of the Paediatric CI Program at the WCHN. In parallel with the governance review, the WCHN committed to a separate independent clinical review for any affected children.

An independent external team with expertise in clinical governance, including a member with significant paediatric CI experience, was assembled from Victoria. SA Health worked closely with the independent external review team (ERT) to define terms of reference (ToR) for the independent clinical governance review. Representatives from SA Health assisted the ERT in obtaining key documents from the WCHN, in setting up the electronic channels to share documents, in facilitation of both internal and external meetings, and in the documentation of staff consultations. Otherwise, SA Health representatives remained completely independent from the ERT.

In compiling this report the ERT requested large amounts of information from the WCHN in relation to the operations of the Paediatric CI Program and information related to the staff within this program. In addition to virtual meetings, the team had an onsite visit to the WCHN in May 2023 and consulted with staff within the program and other relevant staff including executives, CEO and Board Chair. The ERT also had the opportunity to independently reach out to and meet with families of children that had been impacted by the mapping issues. A subsequent visit was made to the WCHN by two members of the ERT in June 2023 to meet in person with several of these families. The report critically appraises the information provided from the WCHN and outlines clearly where the ERT had concerns, with corresponding suggestions for improvement moving forward. Based on their initial review and findings from what had been presented to them, the ERT discussed some preliminary observations with SA Health and the Hon, Minister Picton in June 2023. These observations were subsequently presented to the WCHN team. The WCHN team provided further clarification and evidence including work being undertaken specific to the observations made by the ERT.

Recognising that the underlying cause of clinical incidents such as those that were identified often stem from systems related issues and team culture rather than individuals, the ERT has provided relevant background that they feel is important for context. The report provides significant detail in relation to each of the defined ToR with key recommendations at the end of each individual section. All recommendations are listed below, and significant detail is provided in different sections that address the defined ToR of the report in relation to these recommendations. The report will take readers through the chronology and timeline of the review and the information that was critically reviewed by the team at different timepoints to arrive at the recommendations.

The ERT would like to commend the Paediatric CI team and the Executive team at the WCHN for their openness and transparency in working with the ERT throughout the review. The ERT recognise and acknowledge that this has not been easy and that although necessary, the process has significantly impacted on key staff at the WCHN connected with the Paediatric CI Program. The ERT kept this front of mind during all the staff consultations. The ERT would also like to acknowledge the impact on the children and families affected by the issues and sincerely thank families for coming forward to tell their stories. Many of the stories were confronting for the ERT to hear.

The ERT have no doubt that the staff within the Paediatric CI Program and the Executive team at the WCHN are fully committed to improving the services of the Paediatric CI Program so it can continue to provide high quality, comprehensive and safe care to children and families. The ERT acknowledge that implementing all the recommendations will not be straightforward and will take resources and commitment from the WCHN and the DHW. We believe the recommendations will ensure that families can have confidence that the care they receive at the WCHN in relation to CI and subsequent follow up will be safe and of high quality comparable to relevant benchmark centres. The ERT was provided with the opportunity to make observations about the audiology / CI system more broadly and has taken the opportunity to consider the recommendations that might be adopted across CI programs nationally.

1.2 FINDINGS

The ERT would like to acknowledge the commitment and dedication of all the staff that work within the Paediatric CI Program. Since 2006 there have been significant periods of change within the program with two restructures. Demand for the service has varied year on year and the number of CI surgeries performed each year has reduced in recent years. Nevertheless, the demand for ongoing pre and post op CI care for new and existing patients continued to place a high level of demand on the service throughout these periods of change.

The ERT were alerted to historical cultural issues in relation to certain staff members within the service and significant periods of time when staff within the service were stretched to adequately meet the clinical demand. Audiology CI mapping expertise, particularly in children less than 5 years of age, was reported to be an ongoing issue, and more significant in recent years. Staff turnover has been an issue and the service does not have sufficient Full Time Equivalent (FTE) clinicians and expertise in key areas to meet the current and future predicted demands for a comprehensive service. Short term contracts compound the issue of staff security within the service, a situation somewhat unique to healthcare more broadly in SA because of a mobility clause within certain enterprise agreements. Key recommendations are made in relation to these aspects.

The ERT found and report significant gaps in relation to accurately defined, or the absence of updated models of CI care (pre and post cochlear implant), detailed CI mapping procedures, policies and procedures, competency frameworks for staff working within the program, key performance indicators and documentation related to relationships with external providers. Recommendations are made in relation to these aspects.

In relation to management of the identified mapping issues, the ERT acknowledge the significant amount of work that the team at the WCHN did to determine the scale of the issue and the steps taken to mitigate future risks. However, the ERT report significant concerns in relation to the local management of the issue with tasks allocated to members of the Paediatric CI team that were already overstretched to maintain clinical demand. Although the team somewhat adhered to mandated lookback requirements, no formal process using aggregate clinical incident review methodology was used at the WCHN to determine recommendations to mitigate future risk that could be monitored under the supervision of an appropriate governance committee. The ERT raise significant concerns in relation to aspects of the open disclosure process that was not comprehensive enough. It was the impression of the ERT that both the executive at the WCHN and the Board were satisfied that the issue was being managed at the local level, despite the lack of a unified comprehensive report in relation to the overall incident.

There was no evidence of a close working collaboration with the safety and quality unit at the WCHN and the Department of Health and Wellbeing nor of any oversight committee to monitor completion of the recommendations. This was associated with a lack of accountability in completing allocated tasks within the recommended timeframes and represented an ongoing risk to the service. The fact that the issue was tabled for the first time at the WCHN Significant Events Review Committee (SERC) in June 2023, 12 months after the identification of the original issue, is telling. The ERT make several recommendations in relation to future management of incidents at the WCHN.

The ERT were also keen to make some comments in relation to small niche services that operate within larger centres and what potentially could be done to enhance the level of support provided to these services from a quality and safety perspective.

1.3 SUMMARY OF RECOMMENDATIONS

Existing Cochlear Implant Program at Women's and Children's Health Network (May 2022)

Existing Structure

1. The Women's and Children's Health Network continue to work towards the Children's Audiology Service operating as a united service with clinicians being recognised as having different scopes of practise depending on their skills and knowledge.

2. The Women's and Children's Health Network engage an external skilled facilitator to assist the team in working towards improving team cohesion and collaboration. This must include the Ear, Nose and Throat surgeons who are significant stakeholders in the service and members of the multidisciplinary team.

3. To enable the implementation of current initiatives as well as support the implementation of the recommendations from this review the current manager role be converted from a temporary to an ongoing appointment.

4. Review the current audiologist position descriptions including the key selection criteria so that they reflect the requisite range of practice areas and skills and knowledge required.

Leadership and Culture

5. The Women's and Children's Health Network develop, as a matter of urgency, a set of Key Performance Indicators and audit schedule that is purposeful and provides measurable clinical outcomes and patient/carer experience measures.

6. Key Performance Indicators and audit outcomes are to be reported through formal Women's and Children's Health Network clinical governance committees including the Board Clinical Governance Sub-Committee. These are to be reported to:

- *The Board Clinical Governance Sub-Committee and Executive Safety and Quality Committee initially at the 3- and 6-month mark and then move to an annual reporting cycle unless there is significant variance from targets. If a variance occurs, it must be reported at the next scheduled meeting.*
- *The Allied Health safety and quality committee initially every 3 months and then move to a 6 monthly cycle unless there is significant variance from targets when this variance will be reported at the next scheduled meeting.*

7. Recognising the crucial leadership roles of the Cochlear Implant clinical lead and Children's Audiology Service manager, the Women's and Children's Health Network support their ongoing leadership development through the establishment of individualised plans.

Capacity and Growth in the Paediatric Cochlear Implant Program at the WCHN

8. Clearly map the current and future required capacity of the Paediatric Cochlear Implant Program following:

- *Confirmation of the appropriate model of care.*
- *Confirmation of the staffing profile to adequately deliver the model of care and deal with the patient load.*

9. Implement a contemporary electronic patient booking system that provides for the scheduling requirements across all stages of cochlear implant mapping from switch-on to maintenance.

10. The Women's and Children's Health Network ensure that parents are provided, in the pre-operative phase, written information on the cochlear implant mapping scheduling requirements and that these appointments be booked in advance in collaboration with the parents.

Model of Care

11. The Women's and Children's Health Network must review and document the model of care to ensure that it describes how care will be provided including but not limited to

- *Clearly articulated roles and responsibilities of the Women's and Children's Health Network and the external providers as partners in care. This should include limitations of care at the Women's and Children's Health Network if parents / carers choose to transition care to the external provider/s.*
- *The process for the transition of care between the Women's and Children's Health Network and the external provider/s.*
- *The seamless pathway into and out of the tertiary provider and how concerns can be escalated when they occur.*
- *The workforce required to deliver the model of care.*

12. The Women's and Children's Health Network ensure that there is a formal and responsive multidisciplinary process to discuss candidacy, implantation, progress and when requested by the carer or family facilitate the transfer of care.

Relationships with External Providers

13. The Women's and Children's Health Network and external providers undertake a mediation process to resolve the issues that have arisen and / or been exacerbated because of the recently identified issues with the mapping. This should involve the Department for Health and Wellbeing or be facilitated by the same.

14.The Women's and Children's Health Network develop a process to include external providers in regular case discussions about shared clients – this should be established during the pre-implantation process.

Workforce

15. The Women's and Children's Health Network, as a matter of urgency, ensure a speech therapist with Cochlear Implant expertise is employed as part of the Paediatric Cochlear Implant Program. The full-time equivalent speech therapy staff employed must be sufficient to meet the capacity requirements.

16. The Children's Audiology Service develop a workforce plan that includes succession planning and strategies to address leave and other absences to minimise the use of short-term contacts, disruptions to service delivery and safety and quality risks.

17. The Women's and Children's Health Network work towards ensuring that all Paediatric Cochlear Implant audiologists are credentialled and competent to independently map all children including those under 5 years of age.

18. The Women's and Children's Health Network ensure that it always has more than one Paediatric Cochlear Implant audiologist who is credentialled and assessed as competent to independently map children of all ages, including those under 5 years of age.

Clinical Practice within the Paediatric Cochlear Implant Program

19. The Paediatric Cochlear Implant Program develop templated session notes to ensure consistency of practice and documentation between clinicians.

20. The Women's and Children's Health Network develop a process for peer review including alternating the audiologists working with each child.

21. The Women's and Children's Health Network define Key Performance Indicators for map optimisation and escalation pathways if optimisation is not achieved as scheduled.

22. The Women's and Children's Health Network develop a protocol to formally measure cochlear implant outcomes at defined timepoints and report these outcomes to the multidisciplinary team meeting and to any external provider.

23. The Women's and Children's Health Network develop a standard operating procedure (or protocol) for reviewing unexpected outcomes which includes a definition for unexpected outcome e.g., for older child, able to complete formalised speech perception testing <10% improvement on pre-operative speech perception score, for young children, language progress <70% of peers.

24. The Women's and Children's Health Network develop procedure and escalation pathway for managing complex cases.

Policies, Procedures and Protocols

25. The Women's and Children's Health Network review, as a matter of urgency, all local policies relating to the Paediatric Cochlear Implant Program to ensure that they are current and based on best practice.

26. The Women's and Children's Health Network ensure that all local procedures become part of the central repository of procedures and therefore integrated into the regular review and approval cycles.

27. As part of its audit schedule the Paediatric Cochlear Implant Program include compliance with the visitation schedule, and this is reported to oversight governance committees.

Credentialling, Scope of Practice of Allied Health Staff

28. Paediatric Cochlear Implant audiology be recognised as an advanced scope of practice by the Women's and Children's Health Network. The Paediatric Cochlear Implant audiologists have this advanced scope of practice recognised during the credentialling / recredentialling process by the Allied Health Credentialing and Scope of Practice Committee. This then becomes part of the annual renewal of their credentialing where there is demonstration of ongoing level of competence and skills and knowledge.

29. All Paediatric audiologists working at the Women's and Children's Health Network must be an accredited member of Audiology Australia or working towards accreditation. This will mean that they will meet the annual Continuing Professional Development requirements of Audiology Australia. This will provide evidence to the Allied Health Credentialling and Scope of Practice Committee to facilitate both initial credentialling and then the annual re-credentialing process.

Training, Professional Development and Competency

30. All Paediatric Cochlear Implants Program audiologists have the skills and knowledge matrix assessed and validated by an external expert through the links being developed with other jurisdictional Paediatric Cochlear Implant Programs.

31. The Women's and Children's Health Network update the skills and knowledge matrix to differentiate the competency and skills required to map young children (less than or equal to 5 years of age) versus older children (greater than 5 years of age) given the unique skill set required when working with young children.

32. The Women's and Children's Health Network audiology department develop a structured Continuing Professional Development program.

Identification of the Mapping Concerns

Cluster Incidents

33. In small programs, such as the Paediatric Cochlear Implant Program, that the definition of what number of incidents constitutes a cluster be reduced to less than five cases. A cluster needs to be *considered when three cases of concern are identified or where there is an observable trend. To identify these trends, it is essential that Key Performance Indicators are in place that can be monitored and reported on regularly.*

34. That when a cluster is notified the escalation process involves the safety and quality team to support the lookback, investigation of root causes and the open disclosure process with clearly defined methodologies.

Lookback Review

35. The Women's and Children's Health Network update its Patient incident management and Open Disclosure at the WCHN procedure to align with the South Australian Lookback Review Policy Directive. This update will include, but not be limited to, clear requirements for leadership from the Chair of the Significant Events Review Committee (Executive Director of Medical Service), formal oversight through the Executive Clinical Governance Committee and reporting requirements to the Board Clinical Governance Sub-committee.

36. The Women's and Children's Health Network ensure that all cluster incidents are managed using formal critical incident review methodology with clearly identified recommendations that include person/persons responsible with a delivery date. These must be monitored through the appropriate governance committee to ensure the actions are completed.

Escalation to the Women's and Children's Health Network

37. The Women's and Children's Health Network review its process for information sharing, related to significant / events to the Board and the Board Clinical Governance Sub-committee.

Escalation to the Department for Health and Wellbeing

38. The Department for Health and Wellbeing review their role in the management of significant incidents including clusters particularly around oversight and management.

Communication with the Families

What the External Review Team Heard from Families

39. The Paediatric Cochlear Implant Program ensure that patients and their families are genuine active partners in their healthcare and that they have a formal experience of care and suggestions for improvement feedback mechanism in place.

40. The Paediatric Cochlear Implant Program prioritise work that will enable patients and their families to be genuine active partners in their healthcare.

Open Disclosure

41. The Women's and Children's Health Network offer open disclosure discussions with the families of all children who were determined to be of concern and subsequently had their maps altered.

42. The Women's and Children's Health Network Patient incident management and Open Disclosure at the WCHN procedure be updated to better reflect the requirements of open disclosure when a cluster event is identified as per the current South Australian Patient Incident Management and Open Disclosure Policy Directive.

43. The Department for Health and Wellbeing progress with the update of the eLearn module for open disclosure to ensure it aligns with the Australian Open Disclosure Framework.

44. That the Women's and Children's Health Network considers:

- *Increasing the requirement to undertake the open disclosure eLearn module based on a cascading profile of clinical and leadership roles.*
- *In person simulation training for those leading open disclosure discussions in ISR1 and 2 and cluster events.*

Opportunities for Clinical Governance Improvement or further Change at the Women's and Children's Health Network

Department for Health and Wellbeing

45. Review the Department for Health and Wellbeing's interpretation of the 'devolved governance' model to ensure adequate oversight and explore how the Department for Health and Wellbeing works with Local Health Network Safety and Quality Units including:

- *Reporting that regularly occurs (including key performance indicators)*
- *Reporting that occurs after a cluster event (including key performance indicators)*
- *Reporting after a serious incident (including key performance indicators)*

46. Review South Australia Health's performance monitoring framework and determine with hospitals a set of Key Performance Indicators that increase the focus on quality domains of safety, effectiveness, appropriateness, and patient experience.

47. Department for Health and Wellbeing review the Lookback Review Policy Directive, as a matter of urgency, and ensure that cluster events / incidents are always escalated to the Quality and Safety Unit of the Local Health Network

- *The Local Health Network Safety and Quality Unit is responsible to escalate to the Safety and Quality Unit at the Department for Health and Wellbeing.*

- *Any downgrade of the severity of the incident is overseen by the Local Health Network Safety and Quality Unit.*
- *Any cluster incident or significant event to be tabled at the Significant Event Review Committee within 60 days of the incident.*

Board Governance and Appointment

48. The Department for Health and Wellbeing develop a board orientation program that focuses on the breadth of each board director's obligations particular in relation to safety and quality.

49. The Women's and Children's Health Network Board perform a skills matrix review and develop an education strategy to address any gaps.

50. The Women's and Children's Health Network Board undertake a board culture review to ensure that the board can have robust and respectful discussions and maintain independence from the leadership team.

Singular Cochlear Implant Service

51. The Department for Health and Wellbeing together with the Local Health Networks review the model for the Cochlear Implant Program against other jurisdictions and consider moving towards a single Cochlear Implant service for South Australia which would enable capacity building across the system.

Newborn Hearing Screening

52. The Department for Health and Wellbeing and the Women's and Children's Health Network review the Universal Newborn Hearing Screening Program to improve the effectiveness and alignment with the national Key Performance Indicators.

Minimum Standards for Cochlear Implant Mapping in Paediatrics

53. The South Australian Department for Health and Wellbeing advocate for the development of a consensus statement on the minimum standard for the frequency of mapping of cochlear implants in children in the first 12 months post cochlear implantation. The development of the consensus statement could be led by Audiology Australia.

Minimum Standards of Education

54. All paediatric audiologists at the Women's and Children's' Health Network to work towards advanced paediatric certification with Audiology Australia within the next 12 months.

55. All Paediatric Cochlear Implant audiologists at the Women's and Children's Health Network seek accreditation in the specific Cochlear Implant certification within 12 months of its release.

56. Providers of paediatric hospital-based audiology services consider requiring their staff to obtain advanced paediatric certification with Audiology Australia and accreditation in the specific Cochlear Implant certification following its release by Audiology Australia.

Requirement to be a Member of an Accredited Professional Body

57. Providers of paediatric hospital-based audiology services consider requiring their staff to be accredited members of Audiology Australia.

Consumer Engagement

58. The Women's and Children's Health Network ensure that all their clinical services have processes in place that address parents'/consumer concerns. Parents/ consumers are provided written communication about these processes.

The Way Forward

59. Department for Health and Wellbeing work together with the Women's and Children's Health Network and convene a committee to oversee the implementation of the recommendations adopted from this report.

- *Noting that a small number have wider implications and may not be relevant for the Paediatric Cochlear Implant Program,*
- *The committee comprises representatives from*
    - *Paediatric Cochlear Implant team*
    - *Consumers who are part of the cochlear implant community – parents / carers / previous patients*
    - *Department for Health and Wellbeing.*
- *Progress reports are provided in 3 monthly intervals*
- *Resources are committed to ensure the implementation of the recommendations adopted following this review.*

2. Introduction

2.1 COMMISSIONING OF THE REVIEW

In May 2022 concerns were identified around the mapping of a proportion of children using CIs within the Paediatric CI Program at the WCHN in SA. The concerns were raised by a private provider that provides audiology, speech, and early intervention services as part of a suite of services that children with hearing loss require during their early years. Whilst these concerns appeared to be around children who had been part of the program in the 5 or so years prior, concerns were raised that some of these mapping issues may have gone back as far back as 2006.

The WCHN indicated that it had taken several immediate and remediation steps following identification of the concerns to strengthen the current system including:

- Review of all children who have had CIs since 2006.
- Rectification of deficiencies in mapping of CIs.
- Reviewed the systems and processes within the CI Program.

Despite this, there was continued agitation about the Paediatric CI Program at the WCHN and on Monday, 20 March 2023, the Minister for Health and Wellbeing announced an Independent External Governance Review of the Paediatric CI Program of the WCHN. Alongside this governance review, the WCHN has committed to commissioning a separate clinical review that would look at potential effects of the under mapping on individual children. The ERT understands that the WCHN has now engaged with an interstate external provider to undertake this review.

2.2 TERMS OF REFERENCE

The overarching purpose of the External Governance Review is to:

- understand how and why the problem occurred.
- the system / processes that were (or were not) in place that allowed this to happen.
- reviewing the notification and open disclosure process following the discovery of the error.
- understanding what system changes have been and could be implemented to stop this happening again.
- any opportunities for clinical governance improvement / reform.

2.3 EXTERNAL REVIEW TEAM

The panel consisted of

- Amanda Singleton, Lead Reviewer.
- A/Prof Tom Connell, Executive Director of Medical Services and Clinical Governance and Chief Medical Officer, Royal Children's Hospital Melbourne (RCH).

- Adj Prof Ann Maree Keenan, Consultant.
- Dr Jaime Leigh, Senior Audiologist/Clinician, Cochlear Implant Clinic & Clinical Lead, Victorian Cochlear Implant Program, Royal Victorian Eye and Ear Hospital (Clinical Expert).

2.4 REVIEW PROCESS

The review formally commenced on 1 May 2023, and the final report was delivered on the 9 August 2023.

The Hon. Minister Picton announced an External Governance Review in parliament on the 20 March 2023. A call for public submissions was made on 5 May 2023. The Hon. Minister Picton committed to public consultation being open through to 30 June 2023. This report is based on information gathered by the external review team during:

- Interviews involving staff at the WCHN including clinicians, executive and board members. A discussion guide was provided to staff at WCHN to assist with the types of question that might be asked during the interview process.
- Meetings with families and carers.
- Meetings with external providers.
- Written submissions received during the public consultation process. These were from both families and professional bodies.
- Review of documents provided by the WCHN team.

3. Methodology

3.1 CONFIRMATION OF NUMBERS

At the outset, the ERT attempted to accurately identify the number of children involved in the Paediatric CI program at WCHN since 2006. This included all children who had received care at the Children's Audiology Service at WCHN. As of 11 July 2023, a total number of 208[1] children have been identified as receiving care[2] since 2006. This number includes a small number who received their CI interstate and subsequently transferred their follow up care to the Children's Audiology Service at the WCHN. The Hon. Minister Picton was keen for as many patients / families as possible to contribute to the review and to this end:

- 139 children / families either made contact directly with the ERT through the public consultation or were contacted by registered mail (addresses supplied by WCHN) and invited to contribute.
    - Of the letters sent by registered mail four were returned to sender.
- Families of 69 children that were part of the Paediatric CI program from 2006 were not contacted during the review of the ERT. This was due to either lack of contact details being available or a specific request from the family to have no further follow up.

3.2 INTERVIEWS

The review team undertook an extensive consultation process to understand how and why the Cochlear Implant mapping error may have occurred and the subsequent response from the WCHN.

The review team undertook the following meetings:

- Virtual meetings with staff at the WCHN
    - 1 May 2023.
    - 8 May 2023.
    - 13 May 2023.
- Meetings with WCHN staff and Board members (23 and 24 May 2023)
    - 13 in person meetings total (23 and 24 May 2023).
    - 3 virtual meetings (15 and 29 June 2023).
- Meetings with external providers / representatives
    - In person meeting with representative of Can Do (23 May 2023).
    - Virtual meeting with representatives of Little Allied Health (LAH) (31 May 2023).

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[1] Refer to Appendix 1 for a summary of the children involved in the Paediatric CI Program at the WCHN.

[2] Part of the CI program and received mapping services from the CI audiologists.

  - Virtual meeting with Audiology Australia (5 July 2023).
  - Virtual meeting with Hearing Australia (7 July 2023).
- Meetings with families and carers
  - Virtual group meetings with families and carers (8 June and 26 July 2023).
  - In person one-on-one meetings with families (20 and 21 June 2023).
  - Virtual one-on-one meetings with families (27, 28 June and 3, 26 July 2023).
- Written submissions were received from
  - Hearing Australia.
  - Audiology Australia.
  - Independent Audiology Australia.
  - Australian Association Teachers of the Deaf SA.
  - Little Voices.
  - Families and carers of children with CI.
  - Little Allied Health.

3.3 DOCUMENT REVIEW

The ERT provided to the WCHN an extensive list of the information and documentation that it wanted to review as part of this process on or around 1 May 2023. This included:

- Local Health Network (LHN) policies, procedures and other relevant document provided by the WCHN on 23 May 2023.
- Statewide policy directives from SA Health were provided to the ERT.
- Staffing profiles (audiology and surgeons).
- Training and continuing professional development information / documents.
- Safety learning System (SLS) incident forms, open disclosure discussion forms.
- Minutes of meetings, reports from external experts, and briefing papers.
- Number of implants year on year and number of children included in the program.
- CI Risk Management Database.
- Program data – number of CIs and number of children receiving implants since 2006.

Further documents have been made available from the WCHN throughout the course of the review following additional requests. This information included:

- Further policies, protocols, and procedures.
- Open Disclosure information.
- De-identified clinical notes.

4. Background

According to international literature, moderate to profound (>40 dB) bilateral permanent childhood hearing impairment (PCHI) occurs in 1.3 per 1,000 babies born. Unilateral PCHI of similar severity occurs in 0.6 per 1,000 babies. This suggests that, each year in Australia, approximately 331 children are born with bilateral PCHI, and 174 children are born with unilateral moderate to profound PCHI, a total of 551 children each year with hearing loss[3].

The following section gives some context to hearing loss and aided hearing as the ERT is conscious this report may be widely read and will be made publicly available.

4.1 IMPACT OF HEARING LOSS

It has been suggested that the prevalence of PCHI increases substantially with age. The consequences of the condition include life-long impairment of language skills and possible delays in social development and academic achievement. The severity of the outcome is influenced by the degree and duration of hearing loss, the age at which the hearing loss first appeared, and the hearing frequencies affected. Developmental delays are particularly apparent for children with severe and profound hearing impairment. Children with hearing impairment are more likely to experience lower self-perceived health status than those without hearing loss. Early management of childhood hearing impairment provides many benefits, including improved communication and language ability, mental health, and future employment prospects[4].

The early and varied nature of interventions, treatment and management required for children with hearing loss require an intensive and multidisciplinary approach to their care particularly in the early years. All families of babies with a confirmed hearing impairment, bilateral and unilateral, should be provided with unbiased information on the range of services available, including services provided by Hearing Australia and early hearing intervention services. Families should be referred and have access to these services before their baby is three months of age for advice, including amplification fitting services and cochlear implantation candidacy evaluation. These services should be provided by professionals with expertise in hearing loss and should be available from time of diagnosis to school entry. Early intervention (EI) and management services include both amplification intervention and other EI services provided following diagnosis of a confirmed hearing impairment[5].

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[3] National Framework for Neonatal Hearing Screening, 2013.

[4] National Framework for Neonatal Hearing Screening, 2013, p. 4.

[5] National Framework for Neonatal Hearing Screening, 2013, p. 10.

4.2 MANAGEMENT OF INFANTS WITH HEARING LOSS

Each year between 400 and 500 Australian children are fitted with Hearing Aids (HAs) before their first birthday (approximately 1.9 per thousand live births). Of these children 40 to 50 percent have a bilateral hearing loss of 40 dB 3FAHL or greater[6].

Australian children and their families are provided with a range of government funded supports to assist children who are Deaf and Hard of Hearing (DHH). Citizens or permanent residents have access to fully subsidised hearing services including ongoing audiological management, HAs, remote microphone systems, and associated repairs and maintenance through the Australian government's Hearing Services Program[7]. These services are provided nationally by Hearing Australia. Children who have a permanent hearing loss may also meet access criteria for the National Disability Insurance Scheme (NDIS)[8], which funds supports including specialist EI for hearing loss[9].

4.2.1 HEARING AIDS

Children whose hearing loss is detected through UNHS are referred directly to Hearing Australia for audiological intervention. In 2021, nationally 72.4% of children with bilateral 3FAHL of 40dB or greater, were fitted with HAs by six months of age[10]. In comparison, 33.3% of SA children were fitted with HAs by six months of age for the same period[11]. Hearing Australia facilitates referral to the NDIS and to other specialist services, including CI clinics, specialist EI, otologists, and paediatricians.

Hearing Australia's national protocol states that infants who have been newly diagnosed with hearing loss are offered an appointment at Hearing Australia within two weeks of referral and a fitting appointment is scheduled within two weeks of the family deciding to proceed with amplification. Hearing aids are selected and verified using the approach outlined by King[12], which has been updated to use the NAL-NL2 prescription[13]. The HA prescription is derived from behavioural thresholds that have been estimated from the diagnostic test battery. Within four to six weeks, the fitting is verified according to the

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[6] Hearing Australia. Demographic details of young Australians age less than 26 years with a hearing loss, who have been fitted with a hearing aid or cochlear implant, 31 December 2022.

[7] Australian Government - Department of Health. Hearing Services Program 2022 [Available from: hearingservices.gov.au.

[8] https://www.legislation.gov.au/Details/C2022C00206

[9] National Disability Insurance Scheme. What if my child has just been diagnosed with a hearing loss? www.ndis.gov.au

[10] Hearing Australia. Demographic details of young Australians age less than 26 years with a hearing loss, who have been fitted with a hearing aid or cochlear implant, 31 December 2022.

[11] Hearing Australia. Demographic details of young Australians age less than 26 years with a hearing loss, who have been fitted with a hearing aid or cochlear implant, 31 December 2022.

[12] King AM. The national protocol for paediatric amplification in Australia. International journal of audiology. 2010;49(sup1): S64-S9

[13] Keidser G, Dillon H, Flax M, Ching T, Brewer S. The NAL-NL2 prescription procedure. Audiology research. 2011;1(1):88-90.

protocol outlined by Punch and colleagues[14]. The protocol evaluates audibility of speech stimuli using aided Cortical Auditory Evoked Potentials (CAEP) and the child's listening abilities in real life are evaluated, using the Parent Evaluation of Aural/Oral performance of Children (PEACH)[15]. When aided CAEP tests suggest that the audibility of speech stimuli is inconsistent with expectations, the behavioural audiogram is re-estimated and HAs adjusted.

4.2.2 WHAT IS A COCHLEAR IMPLANT?

A CI is an electronic device that is surgically implanted in the inner ear to help people with severe hearing loss or deafness perceive sound. The device consists of an external sound processor and an implanted electronics package and electrode array.

Cochlear Implant services are state-funded and as such, referral guidelines for infants outlined by CI programs will vary from state to state. Referral for CI candidacy evaluation can occur at several points in the pathway after parental consent.

- At the point of confirmation of hearing loss, when the loss is severe-to-profound.
- When audiological evaluation of the infant's listening skills with HAs indicates that a CI is likely to provide better outcomes.
- When speech and language evaluation or medical evaluation suggest the child's development may benefit from improved access to sound.

For the past decade, when an infant is diagnosed with a bilateral severe to profound hearing loss a simultaneous referral from diagnostic audiology to Hearing Australia for HA fitting and a CI service to commence investigations for CI candidacy is strongly encouraged and is pivotal to enabling CI consideration in children as young as 6 months of age. Referral to a Paediatric CI Program does not always result in CI surgery. Referral guidelines are less conservative than the candidacy guidelines which will be applied by each Paediatric CI Program.

Best practice CI candidacy evaluation involves otological investigations, speech, language and developmental evaluations, and behavioural hearing assessments. The aim of the evaluation is to assess the infant and make a realistic recommendation on the potential benefits of a CI for each child. This, in turn, will ensure that each family can make an informed decision regarding realistic potential benefits available to their child from a CI, in relation to the potential risks. The CI candidacy recommendation process involves careful consideration and co-ordination of audiological, medical, and developmental information. This process is best achieved with the input of a multidisciplinary team (MDT)[16].

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[14] Punch S, Van Dun B, King A, Carter L, Pearce W, editors. Clinical experience of using cortical auditory evoked potentials in the treatment of infant hearing loss in Australia. Seminars in Hearing; 2016: Thieme Medical Publishers.

[15] Punch S, Van Dun B, King A, Carter L, Pearce W, editors. Clinical experience of using cortical auditory evoked potentials in the treatment of infant hearing loss in Australia. Seminars in Hearing; 2016: Thieme Medical Publishers.

[16] Cullington, H. E., Jiang, D., Broomfield, S. J., Chung, M., Craddock, L. C., Driver, S., . . . Vanat, Z. H. (2023). Cochlear implant services for children, young people and adults. Quality standard. Cochlear implants international, 1-13. doi:10.1080/14670100.2023.2197344

Cochlear Implant surgery is performed by an Ear Nose and Throat (ENT) surgeon and typically involves an overnight stay in hospital. Approximately 2 weeks after surgery, the child and family will return to the clinic for the fitting of the sound processor. This first appointment is often referred to as the "switch-on".

Cochlear Implants provide hearing sensations by electrically stimulating nerve fibres within the inner ear (also known as the cochlea). It is important that the right amount of electrical stimulation is used, or the sound heard might be too soft or too loud. Accurate and systematic mapping is required to optimise a child's hearing through a CI. If mapping is not conducted in this way, it could negatively impact on the child's auditory, speech and language development.

Receiving a CI is only the **first step** in a life-long journey for children with congenital hearing loss. To derive optimal benefit from the intervention, technology must be well-maintained and the child, their family and carers supported in its use and optimal communication strategies.

4.2.3 EARLY INTERVENTION (EI)

In parallel to the ongoing and long-term technological support each child with hearing loss receives, is the need for EI and educational support. EI supports for children who are DHH may be funded through the NDIS, State or Territory Education Departments. As a result, all Australian children are eligible to be enrolled in EI services at no cost to the family. EI involves a multidisciplinary approach. The family are viewed as the core member of each child's support team. Professionals in the EI team may include an audiologist, Teacher of the Deaf (ToD), speech pathologist, social worker, and educational psychologist. EI services are offered by both government and non-government organisations. Some EI services may not be able to support all methods of communication. The choice of EI provider will be guided by the family's preference for communication method, their child's age and abilities, and geographical location.

Once a child enters the formal education system, speech, language, and educational support are provided and funded by the Department of Education, usually in the form of a ToD. Families can also access supplementary and personalised support funded through the NDIS. Based on the abilities of the child and individualised goals, the NDIS, will fund a wide range of individual and group therapies.

4.3 DATA ON PAEDIATRIC COCHLEAR IMPLANT PROGRAM AT THE WCHN

4.3.1 BIRTHS IN SOUTH AUSTRALIA[17].

All jurisdictions recorded an increase in birth notifications in 2021. SA had the second largest percentage increase in the country. Applying the rates above, the incidence of children with hearing loss is depicted in Table 1 below.

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[17] Australian Bureau of Statistics, https://www.abs.gov.au/statistics/people/population/births-australia/2021

Table 1: Birth Data 2020 – 2021 Comparison in South Australia

	2020	*2021*	*Change from 20 – 21 (no)*	*Change from 20 – 21 (%)*
Births in SA	**18,574**	**19,783**	**1209**	6.5
Profound hearing loss – total	**35.15**	**37.62**	**2.47**	7
Bilateral PCHI	**24.05**	**25.74**	**NA**	NA
Unilateral PCHI	**11.1**	**11.88**	**NA**	NA

If all these children met the criteria for consideration of a CI, this would give a total of 37 new referrals annually (per annum[18]) or 0.65 per week. This represents a much higher demand than the current data from the WCHN suggests but does not account for children who develop hearing loss as they age.

Not all children with profound hearing loss would receive a CI

- Of those with bilateral PCHI approximately 50% would receive a CI.
- When a child has unilateral PCHI it is more of a parental choice.

4.3.2 NUMBER OF COCHLEAR IMPLANTS IN SA

The WCHN operates the only Paediatric CI surgical program in SA. Prior to 2007, only unilateral implants were offered at the WHCN. Whilst bilateral cochlear implantation was introduced at the WCHN in 2007, prioritisation was still given to funding the first implants for recipients. Children were only considered for a second CI if funding was available after these recipients were managed[19]. In 2009, with good evidence to support bilateral implantation as best clinical practice, the criteria for bilateral implantation were expanded to children who had poor high frequency speech sound detection via HA use in the non-implanted ear. Children under 4 years of age who satisfied the audiological and medical criteria were then routinely offered bilateral implants[20]. Further recommendations occurred in 2010 when sequential and simultaneous bilateral implantation was offered as an option[21].

Since 2006 to year ending 2022 a total of 272 CIs has been implanted in the Paediatric CI Program with an average of 11 per year. These are a combination of unilateral and bilateral CIs. (Figure 1 below).

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[18] based on 2021 birth data.

[19] Bilateral Cochlear Implant, January 2011, Revision of Clinical Protocols (Provided to ERT as Cochlear Implant Protocol 2010- 2016).

[20] Bilateral Cochlear Implant, January 2011, Revision of Clinical Protocols (Provided to ERT as Cochlear Implant Protocol 2010- 2016).

[21] Bilateral Cochlear Implant, January 2011, Revision of Clinical Protocols (Provided to ERT as Cochlear Implant Protocol 2010- 2016).

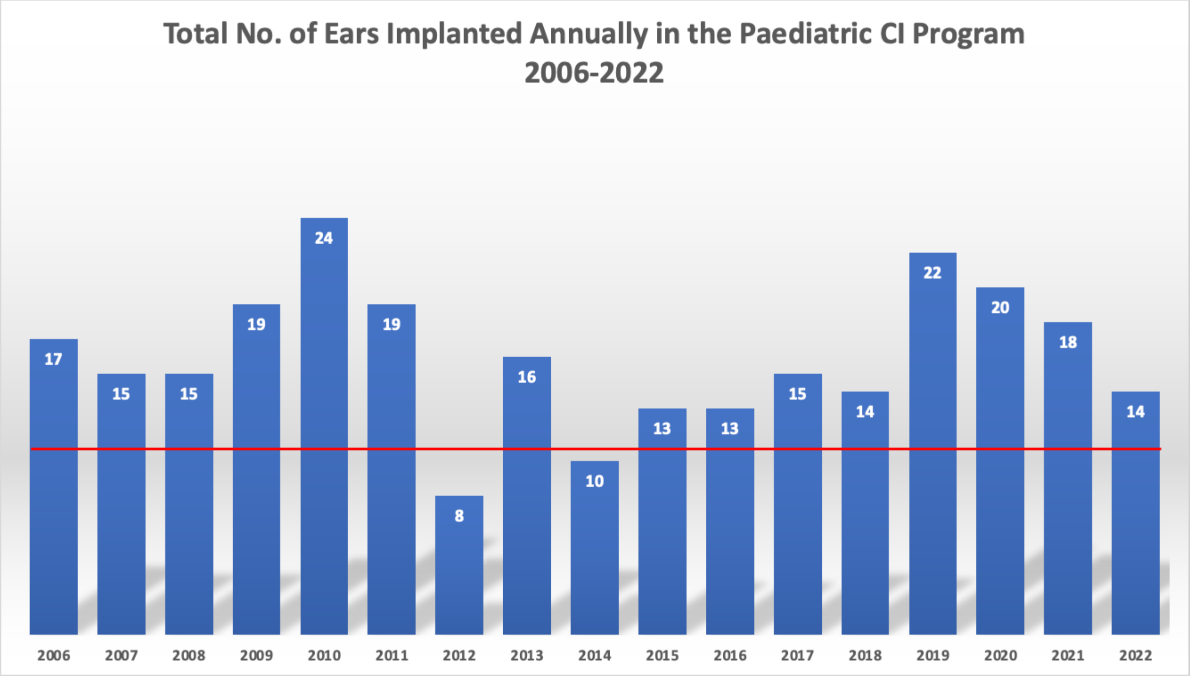

Figure 1: Total No. of Ears Implanted Annually in the Paediatric CI Program (2006-2022)

In 2010, the highest number of 24 CIs was reached in a single year. This corelates with access to bilateral implantation for children with poor high frequency speech sound access via a HA and the children were offered simultaneous bilateral implants[22]. There appears to have been a spike following the expansion of candidacy criteria in 2009, 2010 and 2011 with an average of just over 20 ears implanted per year in this period.

In 2012 there was a significant drop in the number of ears implanted (8 ears implanted). In the following years (2014-2019), the average number of implants was 13 per year. An increase in activity occurred in 2019-21 with an average of 20 implants per year but that number has now reduced to only 14 CIs undertaken in 2022. Over the period (2006-2022), an average of 11 CI has been performed annually at the WCHN (illustrated in Figure 1).

4.3.3 NUMBER OF CHILDREN IMPLANTED

The total number of implants is just one aspect of the total workload for the Paediatric Cochlear Implant Program. As illustrated in Figure 2 the post implant caseload has steadily increased peaking at a total of 131 in 2021, the number declined slightly in 2022 before a more significant drop to 105 in 2023 (year to 13 May). More recent figures supplied to the ERT indicate that the post implant active caseload numbers have reduced further since May 2023[23].

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[22] Bilateral CI Jan 2011 – revision of protocols.

[23] Capacity planning, data, quality, and audit document, WCHN, 11 July 2023.

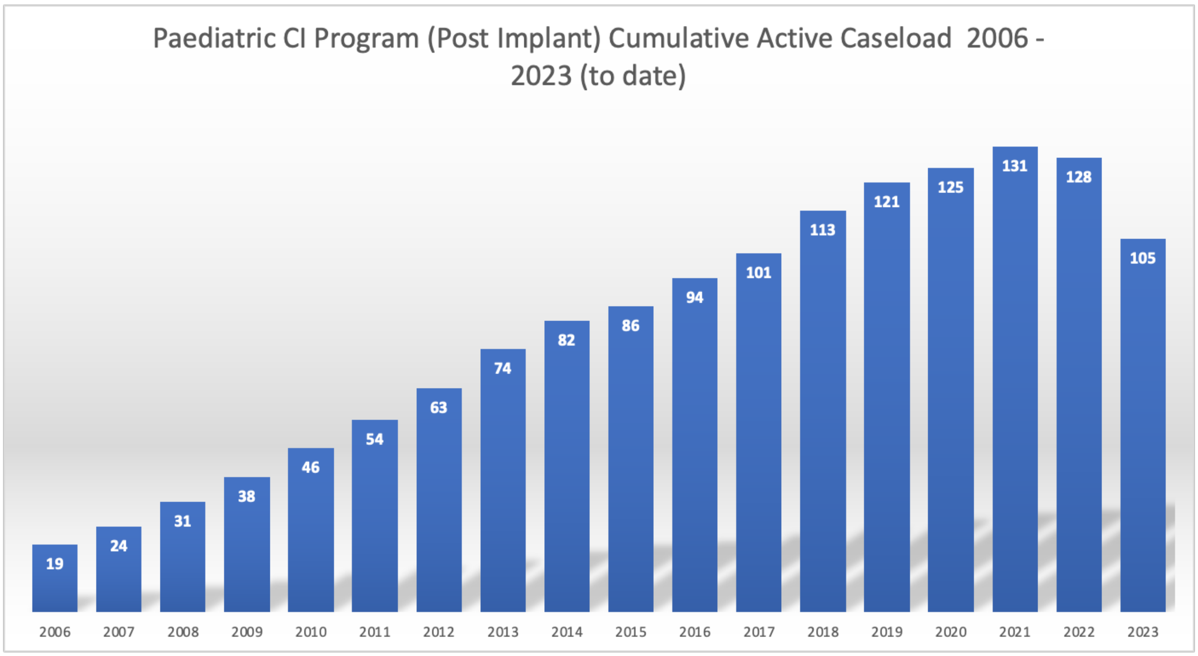

Figure 2: Paediatric Cochlear Implant Program (Post Implant) Cumulative Active Caseload 2006-2023 (to date)

The figure illustrated above (Figure 2) represent the cumulative number of children who are active[24] in the program in any given year. The reason attributed to the more recent decline in numbers are likely multifactorial and include:

- The mapping concerns at the WCHN CI program that has led families to either seek a second opinion or to transfer audiology care.
- Children reaching 18 years of age and transitioned to an adult CI program [e.g., Flinders Medical Centre (FMC), South Australian Cochlear Implant Centre (SACIC)].
- Families / carers becoming or aware of other options since the access to the National Disability Insurance Scheme (NDIS) in 2019.
    - External providers, many of whom are registered through NDIS, offer audiology services including mapping, as well as a holistic approach to care that includes speech therapy and behavioural intervention
    - In line with the principles of the NDIS children or their carers should have the ability to choose how their care is planned and delivered[25] It is noted that the WCHN Children's Paediatric Service doesn't currently include speech therapists as part of the team.

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[24] An active child is one defined as currently received treatment in the Paediatric Cochlear Implant Program.

[25] National Disability Insurance Scheme Act, 2013 https://www.austlii.edu.au/cgi-bin/sinosrch.cgi?method=auto&query=National+Disability+Insurance+scheme+act+

5. Discussion of the Issues

When issues of concern are identified in healthcare, they rarely occur because of a single causal factor and more often occur because of a combination of factors or systems failures. To address the Terms of Reference, the ERT has arranged the report into the following sections.

Each will be explored in Section 5:

- What was occurring in the Paediatric CI Program at the WCHN in May 2022 (when the mapping concerns were identified).
- What occurred at the WCHN at and around the time the mapping concerns were identified including the immediate management, response, and escalation of concerns.
- Communication with families and carers.
- The changes that have occurred as a response to interim feedback from the ERT.
- Opportunities for clinical governance improvement or further recommendations for change at the WCHN.

5.1 EXISTING COCHLEAR IMPLANT PROGRAM AT THE WCHN (MAY 2022)

5.1.1 EXISTING STRUCTURE

The WCHN operates the only Paediatric CI surgical service in SA. The Children's Audiology Services at the WCHN comprises three streams with a total of 6.8 audiology FTE:

- Diagnostic Audiology: electrophysiological hearing assessment.
- Community Audiology: behavioural hearing assessments, visiting services and outreach.
- Hospital Audiology: CI program, ENT support, inpatient, outpatient hearing assessment.

The WCHN Children's Audiology Service includes the Paediatric CI Program. The current structure illustrated below in Figure 3.

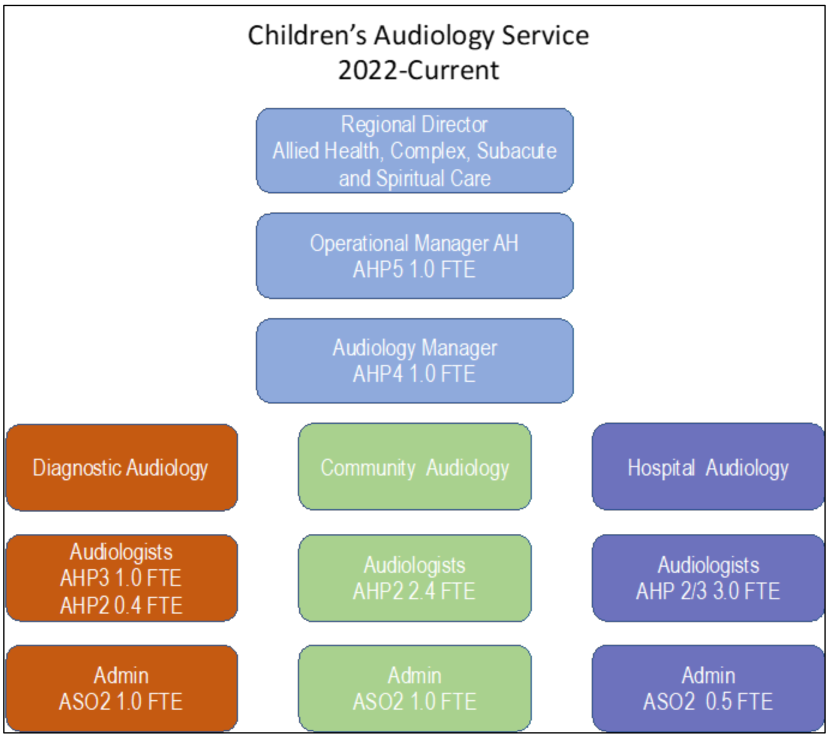

Figure 3: Children's Audiology Service WCHN (2022-Current).

The Children's Audiology Service has undergone restructuring several times since 2016. Up until 2016, the audiology department was managed through surgical services at the WCHN. This included:

- SA Paediatric CI Program.
- ENT support.
- Outpatient services for children and adolescents (0-18 years).
- Inpatient services.

The Newborn and Children's Hearing Program was part of community-based Child and Family Health providing:

- Statewide Newborn Hearing Screening Program.
- Statewide Audiology Services.
- Aboriginal Outreach.

In 2016, the hospital and community audiology merged to form a single Children's Audiology Service. This structure included the Newborn Hearing Program. There was one audiology manager for all services who reported directly to The Regional Director, Allied Health, Complex, Subacute and Spiritual Care (WCHN).

Adequate professional and operational leadership is key to safe and quality healthcare. One aim of this restructure appears to have been to ameliorate the risk of an absence of senior professional audiologist oversight of the CI program by appointing a manager with audiology qualifications. The manager was tasked with bringing the hospital and community audiology services together as one team, to allow staff to increase skill areas and backfill each other's teams based on priority caseloads, whilst also being operationally and professionally accountable for the newborn screening program.

In 2022, a further restructure occurred, separating the Statewide Newborn Hearing Screening Program from the Children's Audiology Service. Each program / service had a dedicated manager. This was in part due to the recognition of the focus needed on both service arms with each requiring a dedicated manager. There was considerable movement at the manager level throughout this period, with at times an acting manager appointed to the Children's Audiology Service. The Statewide Newborn Hearing Screening Program and the Children's Audiology Service now both have dedicated managers in place albeit the manager of the Children's Audiology Service was appointed on a short term 12-month contract in January 2023. The aims of the new structure were to have a pool of audiologists who could work across the range of services. Whilst the Children's Audiology Service has been considered part of one team since 2016, the ERT was told that each area remains very much siloed in their ways of working.

The ERT acknowledges the significant change that has occurred in the service since 2016 with several restructures occurring. This illustrates the instability in the service throughout this period. This was likely a contributing factor to the mapping issues that have been identified.

Restructures take considerable time and effort and this can take the focus and accountability from other important elements in the program such as:

- Development of new or revising existing policies and procedures.
- Development of an audit and quality assurance program.
- Capability building and professional development particularly around the advanced skills required in the CI program.

Recommendations

1. The Women's and Children's Health Network continue to work towards the Children's Audiology Service operating as a united service with clinicians being recognised as having different scopes of practise depending on their skills and knowledge.

2. The Women's and Children's Health Network engage an external skilled facilitator to assist the team in working towards improving team cohesion and collaboration. This must include the Ear, Nose and Throat surgeons who are significant stakeholders in the service and members of the multidisciplinary team.

3. To enable the implementation of current initiatives as well as support the implementation of the recommendations from this review the current manager role be converted from a temporary to an ongoing appointment.

4. Review the current audiologist position descriptions including the key selection criteria so that they reflect the requisite range of practice areas and skills and knowledge required.

5.1.2 LEADERSHIP AND CULTURE

Leadership and culture are recognised as key contributing factors to clinical governance failings across many health service inquiries throughout the world[26].

In the National Safety and Quality Health Service Standards (second edition) clinical governance is the first of the Standards. Leadership and culture sit within the first of the four criteria. Clinical governance is considered 'the integrated systems, processes, leadership and culture that are at the core of providing safe effective accountable and person-centred healthcare underpinned by continuous improvement'[27].

Leaders create and build a culture that supports and promotes excellence in clinical quality and safety. Leaders foster a culture of openness, partnership, learning and continuous improvement and set the tone for how care is delivered and experienced, and the safety and quality outcomes. Leaders are responsible for ensuring that procedures are in place, that there is regular clinical and quality review and there is a program of continuous improvement. Documented audit and peer reviews uncover problems and provide the clinical team with the opportunity to test the validity of concerns.

The Paediatric CI Program had stable clinical leadership in its formative years, and this continued until approximately 2021. Despite this, the Paediatric CI Program did not have clear and up to date procedures for CI mapping, there was no clinical audit process to review outcomes, and no defined program KPIs other than meeting occasions of service activity targets. Up until the identification of the under-mapping issues, there has been no expectation from the WCHN leadership that the Paediatric CI Program have clinical indicators and that these would be reported through the formal WCHN safety and quality structures. Despite the recognition of the need for purposeful KPIs and a program of clinical audit and review[28], at the time of writing, these are yet to be developed, implemented, reported on, and monitored.

Leadership requires both formal and informal skills development. It is unclear to the ERT what leadership training the past CI clinical leads had undertaken. Since late 2021, several staff have acted in the manager and CI clinical lead roles. It is understood the Manager of the Children's Audiology Service remains an acting position, making it challenging for the incumbent to implement required changes and lead the program given the lack of certainty of ongoing tenure. There is some evidence that collectively the current leadership team have undertaken both formal and informal leadership and management development. There is also evidence of engagement with professional bodies.

The role of leader is to provide a safe workplace for staff to be able to raise concerns. The ERT heard conflicting staff views around being provided a safe space to both raise concerns and present new ideas to improve clinical practice. The ERT was told of a past culture of not being able to disagree with the previous long-term clinical lead for the CI program and the individual consequences if there was a difference of opinion.

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[26] Queensland Public Hospitals Commission of Inquiry, Davies 2005, Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry, Francis 2013, Targeting Zero, Duckett, 2016, Independent Review of the Maternity Services at the Shrewsbury and Telford Hospital NHS Trust, Ockendon, 2022.

[27] Safer Care Victoria, Clinical Governance Framework, 2017 p. 6.

[28] Risk Assessment WCHN, February 2023.

Recommendations:

5. The Women's and Children's Health Network develop, as a matter of urgency, a set of Key Performance Indicators and audit schedule that is purposeful and provides measurable clinical outcomes and patient/carer experience measures.

6. Key Performance Indicators and audit outcomes are to be reported through formal Women's and Children's Health Network clinical governance committees including the Board Clinical Governance Sub-Committee. These are to be reported to:

- The Board Clinical Governance Sub-Committee and Executive Safety and Quality Committee initially at the 3- and 6-month mark and then move to an annual reporting cycle unless there is significant variance from targets. If a variance occurs, it must be reported at the next scheduled meeting.
- The Allied Health safety and quality committee initially every 3 months and then move to a 6 monthly cycle unless there is significant variance from targets when this variance will be reported at the next scheduled meeting.

7. Recognising the crucial leadership roles of the Cochlear Implant clinical lead and Children's Audiology Service manager, the Women's and Children's Health Network support their ongoing leadership development through the establishment of individualised plans.

5.1.3 CAPACITY AND GROWTH IN THE PAEDIATRIC COCHLEAR IMPLANT PROGRAM

The Paediatric CI Program in SA is a small program with an average of 11 implants annually (refer Figure 2). Notwithstanding this, the overall demands on the program at the WCHN has consistently increased between 2006 –2022[29]. This increased demand correlates with:

- New children presenting to the service for CI each year – these children all undergo pre-implantation work up within the service
- Number of children who remain in the service for ongoing care following their CI. The senior staff had a distinct preference for the initial mapping (switch on and mapping for the first 12 months to be undertaken at WCHN) as such there has been no active discharge planning to move children away from the tertiary provider to primary care providers.
- There have been attempts to address this more recently and the ERT acknowledge that some of the audiologists recognised the implications of the principles of choice that are apparent in the NDIS.

There have been no additional resources added to the program to manage the demand through to 2022 despite this issue being flagged in 2018 by audiologists working within the program. There have been murmurings over the last five years that staffing was an issue, but the previous long-term clinical lead in the Children's Audiology Service denied that there was a problem, and the issue was never addressed. The lack of adequate resources,

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[29] Figure 2 (Page 32) illustrates the continued upward trajectory of the number of active children in the program.

coupled with the ongoing increased demand evident in the numbers was suggestive to the ERT of a service that was often stretched beyond its capacity to provide safe and comprehensive care.

The ERT was told that parents often had difficulty scheduling and rescheduling appointments. Appointments could be cancelled because of capacity issues including staff illness or leave. In a small clinical program, resources must be aligned to clinical demand and should adapt to meet the ongoing demands of the program. One of the challenges within the Paediatric CI Program has been a lack of templating for appointments. The appointment schedule is not well articulated to parents and therefore they have limited expectation at the outset of what the schedule should look like. Parents are often left to call for an appointment when 'they are ready' rather than a pre - determined schedule, particularly immediately following 'switch on'. The risk here is that some parents may not understand the importance of regular review of their implant and mapping, especially when working towards sound optimisation. Best practice is a schedule of appointments such that you reach optimisation within 3-6 months post switch on.

Recommendations

8. Clearly map the current and future required capacity of the Paediatric Cochlear Implant Program following:

- Confirmation of the appropriate model of care.
- Confirmation of the staffing profile to adequately deliver the model of care and deal with the patient load

9. Implement a contemporary electronic patient booking system that provides for the scheduling requirements across all stages of cochlear implant mapping from switch-on to maintenance.

10. The Women's and Children's Health Network ensure that parents are provided, in the pre-operative phase, written information on the cochlear implant mapping scheduling requirements and that these appointments be booked in advance in collaboration with the parents.

5.1.4 MODEL OF CARE

Children with profound hearing loss require significant intervention in the early years and those that are considered suitable for CI participate in a multidisciplinary model of care that includes audiology, early intervention, Hearing Australia, speech therapy and ENT consultation. Care is provided across multiple settings depending on the child's access to services and the capacity / capability of the service provider. There are different models in place across the country, but each should articulate how the multiple service providers work together in the best interest of the child, including the expectation of transition between the service providers.

There is currently no document that describes how and by whom care is provided and how the model of care is implemented. Most of the documents reviewed[30] by the ERT relate to protocols rather than a comprehensive model of care. These are quite different. Although not adequately documented, the ERT came to the determination that the 'preferred' model of care in the Paediatric CI Program in SA in 2022 was

- Audiology care provided by the WCHN – preoperative audiology workup concentrating on candidacy and readiness for the surgery and post implantation care that focuses on mapping of the implant to optimise the child's access to sound. This has been the preferred service model adopted by the long-term audiologist at the WCHN and the ENT surgeon(s).
- A case co-ordinator (CC) manages the child's journey through the pre and post implantation process. This is consistent with the approach to case management in most CI programs across Australia. A principle WCHN audiologist is allocated as the CC[31]. This is slightly different to programs elsewhere in the country where case co-ordination can be undertaken by other members of the MDT including a speech pathologist. The CC is responsible for overseeing the audiological work-up, liaising with other agencies and is the primary contact for the family in their clinical journey[32]. It is the CC's role to ensure each child has met all the audiological requirements to be considered for cochlear implantation.
- All other services, including speech therapy and early intervention are accessed by the parents through external providers. The ERT was told by parents during this review, that they had two or more external providers involved in the care of their child, often located kilometres apart, requiring a considerable logistical effort to get their child to each service.

In most Paediatric CI Programs, speech therapy is a valued clinical resource within the actual CI team as they work in close collaboration with the audiologists undertaking functional / behaviour assessments during mapping sessions. This is an important element that was missing from the WCHN model of care. Another important member of the team for consideration are the ToD (for those children who engage with these professionals).

The model of care at the Paediatric CI Program suggested significant reliance on a team approach to care and whilst some of that was observed, there is limited evidence of consistent and meaningful collaboration between the WCHN and external providers. Parents report being told that regular catch ups with external providers and the WCHN occurred, but it is unclear how progress was discussed, particularly if the child was complex, and what if any further action was taken when children were not progressing as expected. The ERT was told of an example of a child who failed multiple yearly speech assessments and yet there were no further investigations at the cause including checking the mapping.

One of the risks of having a small program / service is that the model of care is not clearly documented and the knowledge regarding how the model is operationalised relies on

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[30] Cochlear Implant Protocol 2007-2010; WCH Audiology Protocol and Procedure Manual (Cochlear Implant Clinic) 2007-2016 (July 2016); Bilateral Cochlear Implantation (January 2011) - Revision of Clinical Protocols.

[31] Women's & Children's Hospital, Audiology Protocol & Procedures Manual, Cochlear Implant Clinic, 2005-2016.

[32] Women's & Children's Hospital, Audiology Protocol & Procedures Manual, Cochlear Implant Clinic, 2005-2016.

individuals creating a single point of sensitivity. In small programs, particularly those that rely heavily on the external providers to provide a proportion of the care, it is essential to have a well-articulated and a shared understanding of the model of care. This should outline the responsibilities of all parties and needs to be a document that is developed collaboratively.

The ERT saw no evidence of formal documented MDT clinical review. There is currently no structured process to discuss children's outcomes and progress and evidence of critical reflection on test accuracy. There is an apparent lack of critical review of previous test results for children and a tendency to conclude that lack of progress was due to factors related to the child being difficult to test, or not wearing their processor enough, and more intervention was needed at home. A lack of critical review of results and listening to parents' concerns about their child's progress led to delays in identifying concerns, correcting mapping and access to sound potentially leading to long-term impacts for some of these children.

There has been significant tension between professionals within the Children's Audiology Service; some in the team wanted to transition to a model that promotes choice to consumers (parents being able to choose where to attend for their audiology services) and those that wanted to maintain a model where all of the pre implantation work-up, post-implantation switch on, optimisation of the child's sound detection, with all care provided at the WCHN for the initial 12 months post implantation. This tension remained evident during consultations undertaken by the ERT despite some staff being more receptive to having post implantation mapping and care provided by external providers.

Recommendations

11. The Women's and Children's Health Network must review and document the model of care to ensure that it describes how care will be provided including but not limited to

- Clearly articulated roles and responsibilities of the Women's and Children's Health Network and the external providers as partners in care. This should include limitations of care at the Women's and Children's Health Network if parents / carers choose to transition care to the external provider/s.
- The process for the transition of care between the Women's and Children's Health Network and the external provider/s.
- The seamless pathway into and out of the tertiary provider and how concerns can be escalated when they occur.
- The workforce required to deliver the model of care.

12. The Women's and Children's Health Network ensure that there is a formal and responsive multidisciplinary process to discuss candidacy, implantation, progress and when requested by the carer or family facilitate the transfer of care.

5.1.5 *RELATIONSHIPS WITH EXTERNAL PROVIDERS*

External providers form a fundamental component of most Paediatric CI programs across the country. In SA paediatric audiology, speech and / or early intervention services are provided by the following[33]:

- Little Allied Health.
- Can: Do 4 Kids.
- Department of Education.
- Good Prospects.
- Adelaide Paediatrics.
- Rainbow Audiology.
- SA Speech and Hearing Centre.
- Hearing Australia.

Many of the audiologists working at or for external providers have formally worked at WCHN in the Children's Audiology Service and are well known to the WCHN team. It was reported to the ERT that there is a long history of tensions with WCHN and external providers. Tensions between the entities have increased in recent years as external service providers have agitated for earlier involvement in the mapping of children's implants and WCHN have maintained the current status quo that the switch on, optimisation and first twelve months of mapping should be undertaken exclusively by the WCHN team. This tension appears to have exacerbated since the introduction of the NDIS and its use in the audiology context from around 2019.

All parties told the ERT that the relationship is difficult and the tensions between some of the parties remain problematic. This even extends to each party questioning the others clinical abilities and expertise in the audiology space. What is clear is that the best interest of the children must be the core principle of any service provided and given the reliance on private providers particularly in the early intervention space, there should be a seamless transition of patients and information between all parties. Importantly, the NDIS legislation[34] outlines as part of its objectives that people with a disability should be able to exercise choice and control in the pursuit of their goals and the planning and delivery of their supports. This should also include choice when it comes to the mapping of their implants[35].

It is in everyone's interest for the Paediatric CI Program and the private providers to work together to provide the best model of care possible for each child. In some cases, this means that a child may have little, if anything to do with the WCHN following cochlear implantation. The WCHN has an obligation to inform families and carers of all available options and not to stand in the way when a parent or carer decides to receive care external to their service. Parent should be informed of the expected schedule of appointments

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[33] Note not all services are provided at each of these providers.

[34] https://www.legislation.gov.au/Details/C2022C00206

[35] National Disability Insurance Scheme Act, 2013, s 3(1)(e).

following cochlear implantation to ensure that optimisation occurs within the expected timeframe, and this should be documented clearly in the model of care.

Recommendations

13. The Women's and Children's Health Network and external providers undertake a mediation process to resolve the issues that have arisen and / or been exacerbated because of the recently identified issues with the mapping. This should involve the Department for Health and Wellbeing or be facilitated by the same.

14. The Women's and Children's Health Network develop a process to include external providers in regular case discussions about shared clients – this should be established during the pre-implantation process.

5.1.6 WORKFORCE

The Paediatric CI Program sits within the overall Children's Audiology Service at the WCHN. The Children's Audiology Service has a manager (1.0 Full Time Equivalent (FTE)), audiologists, (6.8 FTE), family support coordinator (0.8 FTE) and administrative support (2.5 FTE).

The **Paediatric CI Program** has historically run with a team that includes:

- Ear Nose and Throat (ENT) surgeons - responsible for preoperative medical investigations and preparation of the child, the surgical procedure and postoperative medical care. There are currently three employed at WCHN who undertake cochlear implants with the majority being undertaken by one surgeon (2022).
- Audiologists - responsible for provision for pre surgery audiology workup, switch on and initial mapping through to optimisation. They provide ongoing audiology maintenance of the implants for children who remain with the WCHN for their ongoing audiology care. There are currently 3.0 FTE audiologists in the Paediatric CI program. These audiologists have varied experience with not all being able to program implants for children of all ages independently.
- Administrative support role that includes amongst other things scheduling of clinic appointments when requested by parents. There is currently 0.5 FTE in the Paediatric CI program.

The **Children's Audiology Service** is supported by a Family Support Coordinator. The incumbent has a clinical background as a social worker. This is a statewide role that has been in existence for many years[36]. This role focuses on children, aged 0-7 years with permanent hearing loss, in the initial period post diagnosis by providing general support and assistance with early intervention discussions. These discussions include options of community-based providers of EIP's. This role has **very limited engagement** with the CI program.

As Table 2 illustrates, the budgeted FTE for the Paediatric CI Program CI has remained at 3.0 Financial Year (FY) 18-22). When there has been a reduction in the availability of staff

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[36] On the advice of Hearing Australia

because of planned leave backfill of the positions has not been available. This is primarily due to the specialised skills that are required in the Paediatric CI Program. Adjustments were made to the workload during this time with audiologists from other areas of the Children's Audiology Service providing care to non-CI patients. The ERT was told that there had been requests for increased resources, by the audiology team, including more senior clinicians, but this had not been supported by the previous long term clinical lead. Paediatric CI audiologists are advanced clinicians and should be employed for their expertise and recognised at the appropriate Allied Health Professional 3 (AHP3) classification.

Table 2: Cochlear Implant Audiologist Full-time Equivalent (FTE) - 1/7/2017-30/6/2022

Financial Year	Budget	CI Staff FTE	No CI Staff FTE	Notes
FY 18	3.0	3.0	0.0	Total of 4 audiologists
FY 19	3.0	2.4	0.6	Maternity leave – no CI trained staff to backfill, Audiology staff working at WCH providing audiology service to non-CI patients
FY 20	3.0	2.1	0.9	Maternity leave and LSL– no CI trained staff to backfill, Audiology staff working at WCH providing audiology service to non-CI patients
FY 21	3.0	3.0	0.0	CI staff on board but in training, had limited caseload
FY 22	3.0	3.0	0.0	CI staff on board but in training, had limited caseload

Speech therapists have not been part of the Paediatric CI team. The ERT was told that accessing speech therapists both within the WCHN and externally is very challenging. The model of care in most Paediatric CI Programs includes speech therapists working in close collaboration with the audiologist during mapping sessions. This was raised with the WCHN during the review and this deficit is currently being addressed.

Of some concern to the ERT was that since 2016, there has been no increase in the audiologist staffing levels across the Paediatric CI Program despite the increase in caseload and lack of discharge criteria and planning (refer Figure 3). In mid 2022, the WCHN acknowledged the pressure from the growing patient numbers in the Paediatric CI Program in a brief to the Hon Minister for Health and Wellbeing[37] as well as during an internal clinical risk discussion with a need to support a commissioning bid to review resources to sufficiently service the Paediatric CI caseload[38]

From the perspective of the ERT, there appears to be a disconnect between having sufficient FTE and having staff who are trained sufficiently to undertake mapping. The current state is such that there remains a gap in the service, as some of the current CI audiologists cannot undertake mapping 'independently' for children less than 5 years of age. The mapping of children has therefore been reliant on a small number of CI

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[37] Brief to the Minister for Health and Well-Being 26/8/22.

[38] Clinical Risk Discussion 28/7/22.

audiologists with at times, only one person deemed competent to map this younger cohort less than 5 years of age. As a result, it is challenging to have a range of clinicians assess and adjust a child's map as is best practice. This is compounded by staff absences due to staff turnover, maternity leave and long service leave and regular unplanned absences.

The ERT was told of the challenges in recruiting and retaining staff due to the use of multiple short-term contracts. This is something of a challenge across SA Health due to conditions in enterprise agreements. The use of short-term contracts includes the current Children's Audiology Manager who was appointed on a short-term contract. There was uncertainty as to the reason for the use of this short-term contract especially considering the 2022 restructure.

Recommendations

15. The Women's and Children's Health Network, as a matter of urgency, ensure a speech therapist with Cochlear Implant expertise is employed as part of the Paediatric Cochlear Implant Program. The full-time equivalent speech therapy staff employed must be sufficient to meet the capacity requirements.

16. The Children's Audiology Service develop a workforce plan that includes succession planning and strategies to address leave and other absences to minimise the use of short-term contacts, disruptions to service delivery and safety and quality risks.

17. The Women's and Children's Health Network work towards ensuring that all Paediatric Cochlear Implant audiologists are credentialled and competent to independently map all children including those under 5 years of age.

18. The Women's and Children's Health Network ensure that it always has more than one Paediatric Cochlear Implant audiologist who is credentialled and assessed as competent to independently map children of all ages, including those under 5 years of age.

5.1.7 CLINICAL PRACTICE WITHIN THE PAEDIATRIC CI PROGRAM

Prior to 2023, the approach to mapping at the WCHN was not well defined, documented or consistently applied with some practices considered ineffective and not reflective of contemporary mapping approaches. From the review of clinical records, the ERT observed notable variation in the approach to mapping amongst audiologists in the program. This was likely confounded by the absence of an up-to-date mapping protocol. The ERT are aware that an updated mapping protocol has been drafted and the WCHN are currently seeking external review and endorsement of this protocol.

Clinical practice demonstrated a notable emphasis on the measurement of the aided audiogram in postoperative appointments for children implanted at the WCHN. The aided audiogram appeared to be the primary tool used to verify and validate the child's map and was consistently used to guide adjustments to T and C levels[39]. Aided audiogram will provide confirmation of the level of sound detected and can be expected to be measured at

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[39] Definitions for T and C levels can be found in the Definitions in terms

≤25dBSPL across frequencies associated with speech sounds (500, 1k, 2k and 4kHz)40 for a CI recipient, so long as mapping levels (T & C levels) have been set within the audible range. The aided audiogram is limited to providing information about the child's response to low level sound and does not provide an indication of performance to moderate levels. That means that if a child with a CI is unable to achieve aided thresholds within the expected range (≤25dBSPL), it is possible that T-level have been set too low and may warrant adjustment. The aided audiogram is an ineffective way to inform adjustments required to C-levels and, when used in isolation, does not determine optimisation of the map.

Persistent measurement of aided thresholds within a mapping session runs the risk of over testing a child and would compromise the ability to behaviourally measure T & C levels within the same appointment. Setting T and C levels behaviourally is widely accepted as the gold standard amongst experienced CI programs who engage audiologists. The emphasis on obtaining the aided audiogram may have contributed to the prolonged period observed to achieve map optimisation for some children at the WCHN. Review of recent clinical records for four children who have received a CI at the WCHN during 2022 suggested that three of the four children had not achieved map optimisation by 12 months post-operative, as evident by the continued use of progressive maps in the child's sound processor. Typically, map optimisation for a child would be achieved within 3-6 months following cochlear implantation.

The WCHN reported that principally two audiologists were involved in mapping appointments for young children. Involving two clinicians is consistent with the approach used and recommended by experienced CI programs, however most programs would utilise a one audiologist and one speech therapist or habilitationist rather than a two-audiologist model. The involvement of two clinicians within a mapping appointment enables the primary clinician to focus on presenting stimulation to the child using the custom programming software and subsequently set the mapping levels. The second clinician's role is to moderate the child's response state and provide feedback on their observations of the child to the primary clinician. The involvement of two clinicians within the appointment does not suffice as a peer review given the second clinician is typically blind to the level of stimulation and decisions being made by the primary clinician. At the WCHN the primary clinician for a child was frequently the same clinician for extended periods, as is consistent with the case co-ordinator model used. This resulted in no peer review of mapping for children attending the WCHN.

Functional measures of listening form a crucial component of verifying the appropriateness of a child's map and quantifying their auditory skills. Functional measures were noted to be used during CI mapping appointments at the WCHN. However, variability was noted in the choice and application of functional measures. Monitored live voice presentation of speech perception material, as used with older children at the WCHN, has been demonstrated to have high variability across tests and significantly inflated speech recognition scores completed to tests completed using recorded stimuli[41]. Functional measures were rarely

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[40] Hawkins, D. B. (2004, February). Limitations and uses of the aided audiogram. In Seminars in Hearing (Vol. 25, No. 01, pp. 51-62). Copyright© 2004 by Thieme Medical Publishers, Inc., 333 Seventh Avenue, New York, NY 10001, USA.

It is noted that these are accepted audiological parameters.

[41] Uhler, K., Biever, A., & Gifford, R. H. (2016). Method of speech stimulus presentation impacts pediatric speech recognition: monitored live voice versus recorded speech. Otology & Neurotology, 37(2), e70-e74.

referenced against expected performance. Functional measures are available which allow a child's auditory skills to be quantified beyond the detection of sound. It is important that an outcome evaluation involves well-validated, clinically feasible monitoring protocols to track auditory development. Several tools have been validated and are within the scope of an audiologist's practice e.g., FLI-P[42], IT-MAIS[43], LittleEARS[44], PEACH[45].

There does not appear to be a protocol or procedure in place which describes how children's outcomes are quantified and evaluated. There is reference to a 12-month post-op evaluation in the "Flow Chart – Post-operative" provided to the ERT[46], but no details as to what this entails aside from a reference to utilising those tests pre-operatively. Receptive and expressive language development as well as speech perception and production are important aspects of outcome evaluation. Outcomes need to be formally reported to a multidisciplinary forum and a process in place to investigate unexpected progress. Due to the small nature of the program and inherent limited exposure to complex cases, it is not unexpected that the Paediatric CI team were not well equipped to independently resolve complex cases.

Frequency and number of postoperative appointments offered and attended by families was observed to vary considerably from one child to another. This variability was also reported by parents of children who received a CI at the WCHN and who were interviewed by the ERT. It was reported to the ERT that there were no robust appointment booking processes in place in the early post-operative period and it was frequently left to the family to contact the service to arrange their next appointment. Review of clinical records confirmed this variation in the schedule of post-operative mapping appointments.

Recommendations

19. The Paediatric Cochlear Implant Program develop templated session notes to ensure consistency of practice and documentation between clinicians.

20. The Women's and Children's Health Network develop a process for peer review including alternating the audiologists working with each child.

21. The Women's and Children's Health Network define Key Performance Indicators for map optimisation and escalation pathways if optimisation is not achieved as scheduled.

22. The Women's and Children's Health Network develop a protocol to formally measure cochlear implant outcomes at defined timepoints and report these outcomes to the multidisciplinary team meeting and to any external provider.

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[42] Davis, A., Harrison, E., & Cowan, R. (2022). The Feasibility of the Functional Listening Index—Paediatric (FLI-P®) for young children with hearing loss. Journal of Clinical Medicine, 11(10), 2764.

[43] Osberger, M. J., Geier, L., Zimmerman-Phillips, S., & Barker, M. J. (1997). Use of a parent-report scale to assess benefit in children given the Clarion cochlear implant. The American journal of otology, 18(6 Suppl), S79-80.

[44] Weichbold, V., Tsiakpini, L., Coninx, F., & D'haese, P. (2005). Development of a parent questionnaire for assessment of auditory behaviour of infants up to two years of age. Laryngo-rhino-otologie, 84(5), 328-334.

[45] Ching, T. Y., & Hill, M. (2007). The parents' evaluation of aural/oral performance of children (PEACH) scale: Normative data. Journal of the American Academy of Audiology, 18(03), 220-235.

[46] Women's and Children's Hospital Audiological Protocol and Procedure Manual, Cochlear Implant Clinic (2007-2016).

23. The Women's and Children's Health Network develop a standard operating procedure (or protocol) for reviewing unexpected outcomes which includes a definition for unexpected outcome e.g., for older child, able to complete formalised speech perception testing <10% improvement on pre-operative speech perception score, for young children, language progress <70% of peers.

24. The Women's and Children's Health Network develop procedure and escalation pathway for managing complex cases.

5.1.8 POLICIES, AND PROCEDURES / PROTOCOLS

The devolved governance structure in SA means that policy directives produced and disseminated by SA Health are made available to the LHN with the expectation that local policies / procedures substantively reflect any statewide directive. The WCHN made policies and protocols available for the ERT during the review.

Of concern for the ERT is that many of the protocols relevant to the CI program were:

- More consistent with policy statements
- Historically provided limited direction on the actual mapping procedures, including frequency. Two procedures provided by the WCHN included protocols for CI.
    - The first, encompassed the protocol for 'mapping' from Jan 2005 through to July 2016 with updates noted in Oct '05, June '06, Dec '06, Feb '07, Mar '08, Nov 09, Jan 11, June 14, and July 2016. It is assumed that the July 2016 protocol was the reference document in place from 2016 through to 2022.
    - The only direction on mapping frequency was found in a flow chart attached at the back of the protocol but according to case notes this is not adhered to.
    - 2016 protocol suggest that the CC is responsible for deciding how frequently a child should be mapped. The protocol includes factors likely to influence frequency of appointments but there is no indication as to the criteria that is used to guide this decision.
    - The protocol describes aims of the mapping appointments but no detail on steps conducted to achieve these aims. Staff interviewed indicated that the culture of the unit was one that emphasised that patients were unique, and that frequency of mapping would be determined by the audiologist rather than following a procedure to guide practice.
    - The second, The Clinical Procedure: Paediatric Cochlear Implant Mapping, with a date of 23/09/2022, remains in draft, even after issues have been identified but it does provide a more detailed and contemporary approach to mapping-commenced after the events.
- The policy for transfer[47] of children to external providers was in a draft format. Families reported challenges in achieving transfer and access to information from WHCN to facilitate seamless care.

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[47] Clinical Procedure: Transfer of Paediatric Cochlear Implant Audiology Care to Private Providers, V 4, 23 March 23.

- No escalation policies or procedures for children who are not making the expected progress following cochlear implantation.
- No evidence of audits to ensure compliance with protocols.

The protocols of the Children's Audiology Service are only held on the local drive and not on the WCHN intranet therefore they are not part of an overall document control process that prompt review and endorsement through the correct committee structure[48]. The absence of up-to-date policies and procedures that are in line with best practice is a failing of the Paediatric Cochlear Implant program. The ERT were told that policies and procedures were previously deemed unnecessary and that at times it was not safe to raise the need to update policies and procedures or question clinical practice. Even when a local protocol existed there is evidence that it has not been followed. The 2016 Protocol for long-term follow-up states that the "CC shall review each child's aided hearing at three monthly intervals once hearing has been optimised and map stability has been achieved".

Recommendations

25. The Women's and Children's Health Network review, as a matter of urgency, all local policies relating to the Paediatric Cochlear Implant Program to ensure that they are current and based on best practice.

26. The Women's and Children's Health Network ensure that all local procedures become part of the central repository of procedures and therefore integrated into the regular review and approval cycles.

27. As part of its audit schedule the Paediatric Cochlear Implant Program include compliance with the visitation schedule, and this is reported to oversight governance committees.

5.1.9 CREDENTIALLING AND SCOPE OF PRACTICE OF ALLIED HEALTH STAFF

There is a requirement for all allied health staff to be credentialled by SA Health[49]. SA Health is committed to ensuring that all Allied Health Professionals (AHPs) undertaking allied health-related work have the appropriate and recognised credentials to provide services relevant to their area of professional responsibility. This includes all allied and scientific health professionals employed or prospectively employed and all non-employees with contractual or other arrangements allowing them to work on SA Health sites, provide services on behalf of SA Health, or access SA Health patient information systems. Regardless of employment status, all registered, self-regulated or unregulated professions providing allied health related services must comply with this policy. Initial authentication and re-authentication of credentials of health professionals are key corporate and clinical governance responsibilities undertaken by each health facility in each LHN, government or professional body to ensure that all practising AHPs are appropriately qualified.

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[48] WCHN Tier 2 Procedure Governance Committee (Sept 2019).

[49] Credentialing for Allied & Scientific Health Professionals Policy Directive, Policy No.: D0226, Version No.: 3.4, Approval date: 21/02/2020.

The WCHN's own procedure for credentialling and scope of practice for Allied Health (AH) was approved in November 2022[50]. This is the original procedure, there was no evidence, prior to 2022, of organisational oversight of the Paediatric CI Program audiologists' credentials and scope of practice. This may be associated with some vulnerability where practitioners are operating outside of their scope of practice, skills, and knowledge level. Key components of the procedure include:

- All primary AH practitioners (self-regulating professions) must provide evidence of academic achievement from an accredited university course when first credentialled for practise.
- An AH practitioner must provide eligibility for membership of the relevant professional association.
- AH practitioners in a self-regulated profession must provide evidence that they meet the **scope of clinical practice** to be credentialled to practice in a particular clinical area by way of additional qualifications or evidence of competency.

The WCHN identified AH credentialling as an issue following an internal audit in 2019[35]. In 2021 a dedicated credentialing officer role was created, which enabled central coordination and management of AH credentialing for the network. A robust database of all AH professionals across the network was created. This is updated through the ongoing human resource processes. No new contract is issued without evidence of credentialing. In 2022, WCHN commenced a routine audit schedule to assess compliance with AH credentialing.

Whilst the audiologists might be credentialled to practice generally, that is they hold the correct academic qualifications to undertake audiology, there was no evidence provided to the ERT that the credentialling process considers the scope of practice for each of the clinicians. As the ERT found there is no documented evidence about the scope of practice for each audiologist. On the available evidence the ERT could not determine which audiologist had the qualifications, skills, or competency to undertake CI mapping of children and in particular those < 5 years of age, which is deemed a more nuanced skill set.

The credentialing procedure requires annual re-credentialing. The process includes reconfirming registration, eligibility for professional association membership, experience, continuing professional development, scope of practice and professional standing. The credentialling process is also used to confirm that the applicant has received appropriate support and supervision, completed a Performance Review and Development plan and mandatory training requirements. Outside of the annual process of re-credentialing, when there is alteration to the scope of clinical practice, there is a further opportunity to have this scope of practise formally recognised[51]. This provides the opportunity for Paediatric CI Program audiologists who reach any higher level of competence to be credentialed in this scope at any time of the year. This process, if adhered to, appears robust but unfortunately the WCHN has not followed its own credentialling and scope of practice procedure.

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[50] Credentialing and Defining Scope of Clinical Practice of Allied Health Professionals, document number sp2022_023, Approved 18 November 2022.

[51] Credentialing and Defining Scope of Clinical Practice of Allied Health Professionals, document number sp2022_023, Approved 18 November 2022.

The time to achieve independence is indicative of the skill level and advanced scope of practice required of a Paediatric CI Audiologist. Given this, it would not be unreasonable to expect that this be covered in the advanced scope of practice component of the credentialing and scope of practice policy. To be recognised and credentialed in advanced scope of practice requires the completion of the AH Credentialing and Scope of Practice application form. The ERT was not provided with evidence that any of the CI Program audiologists have applied for this advanced scope of practice through the AH Credentialing committee.

Recommendations

28. Paediatric Cochlear Implant audiology be recognised as an advanced scope of practice by the Women's and Children's Health Network. The Paediatric Cochlear Implant audiologists have this advanced scope of practice recognised during the credentialling / recredentialling process by the Allied Health Credentialing and Scope of Practice Committee. This then becomes part of the annual renewal of their credentialing where there is demonstration of ongoing level of competence and skills and knowledge.

29. All Paediatric audiologists working at the Women's and Children's Health Network must be an accredited member of Audiology Australia or working towards accreditation. This will mean that they will meet the annual Continuing Professional Development requirements of Audiology Australia. This will provide evidence to the Allied Health Credentialling and Scope of Practice Committee to facilitate both initial credentialling and then the annual re-credentialing process.

5.1.10 TRAINING, PROFESSIONAL DEVELOPMENT AND COMPETENCY

To become an audiologist in Australia requires the completion of a relevant bachelor's degree followed by two-years in an Audiology Australia (AudA) accredited Master level audiology program. Audiology Australia is the relevant professional body for hospital employed audiologists having approximately 3500 members. To be eligible for the annual accreditation with AudA requires an additional one-year internship and to maintain accreditation the audiologist must be able to provide evidence that they have participated in a minimum relevant professional development over the previous 12 months[52]. Although not a registered health profession with the Australian Health Professional Registration Authority (Ahpra), AudA requires its accredited members to adhere to a set of standards that are consistent with those that are deemed necessary for health professionals registered through the Ahpra.

The WCHN do not require audiologists to be **accredited** members with AudA or any other audiology professional body. The procedure[53] merely indicates that the audiologists be eligible for membership of the professional body. This differs from the requirements of many other tertiary and specialist health services in other jurisdictions. Accredited

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[52] https://audiology.asn.au/Consumer_Hub/About_Audiologists/Qualifications_and_training

[53] Credentialing and Defining Scope of Clinical Practice of Allied Health Professionals, document number sp2022_023, Approved 18 November 2022.

membership would provide a level of checking that the audiologist has met the professional body's professional development requirement which includes providing evidence of same.

The ERT explored how clinical skills are developed within the Paediatric CI Program. There has been a reliance, over many years, on one audiologist to train new audiologists. In addition, training has been provided by the CI manufacturers particularly around the development of competencies and knowledge on the technical aspects of the implants. Whilst it is not unreasonable to seek education from company representatives, there is also an expectation that education would be sought from other sources. Some staff did report access to Continuing Professional Development (CPD) events including conferences. No staff mentioned keeping up to date with clinical practice through avenues such as a journal club, journal articles and reviewing research literature.

Since 2014 the WCHN have had a knowledge and skills matrix (the matrix)[54] for the Children's Audiology Service. The detailed matrix provides a description of competency levels from a novice to independent practitioner. The matrix describes a process of an initial assessment of skills within the first 1-2 weeks of employment. This is then reviewed at the end of the 6-month, 12-month, 24 month and 36-month work periods with a date of assessment recorded for each period of review entries. The matrix specifically references the knowledge and skills required to be deemed independent, as an audiologist, in the Paediatric CI Program with the expectation that the clinician will be competent at approximately 18–24-month period and independent between the 24–36-month period. Based on what the ERT was told there is an assumption that at this latter period the clinician will be deemed independent and competent to undertake mapping for children of all ages. The matrix does not differentiate competency related to age of children whereas the Pediatric CI Program staff differentiate competency according to the age of children i.e., less than and over 5 years of age. There is an acceptance that mapping of CI for children <5 years of age is a more nuanced skill.

The matrix is "intended to show the new audiologist's progress over time. The initial assessment dates will remain on the matrix and subsequent assessment dates will be added at the end of each review". The ERT was told during the interviews by some audiologists that they had not seen the matrix and those that had seen it reported that they had not been assessed against the competencies. The ERT was also told that once completed the matrix was not revisited as a means of validation for ongoing competency at the independent level. Key to CI skill development is the 'at elbow' training as well as consistent exposure to practice to maintain CI mapping skills. Whilst the program has grown the number of children receiving implants has remained small thus making it challenging to both build and maintain the requisite skills to work independently in the Paediatric CI program. The matrix states that it will take 24-36 months to become independent across all aspects of the Paediatric CI program. This timeline for independence is consistent with the expectations within other jurisdictions however many of these jurisdictions have larger programs and thus more exposure for each clinician.

The Paediatric CI Program appears to have a reliance on training and not necessarily on the competence and skills of the audiologists. As part of any program competency assessment is key to ensure that all clinicians possess not only the training to undertake a task but skills and capability to work in a specialised area. The ERT were told that

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[54] Women's and Children's Hospital (WCH) Audiology Knowledge and Skills Matrix, January 2014.

previously one of the Paediatric CI audiologists had their competency signed off as independent within 12 months of commencing at the WCHN. This is inconsistent with the expectations set out in the matrix. The ERT would expect there would be progressive competency assessment and skills acquisition over several years and that the skills matrix would be revisited annual after that.

Recommendations:

30. All Paediatric Cochlear Implants Program audiologists have the skills and knowledge matrix assessed and validated by an external expert through the links being developed with other jurisdictional Paediatric Cochlear Implant Programs.

31. The Women's and Children's Health Network update the skills and knowledge matrix to differentiate the competency and skills required to map young children (less than or equal to 5 years of age) versus older children (greater than 5 years of age) given the unique skill set required when working with young children.

32. The Women's and Children's Health Network audiology department develop a structured Continuing Professional Development program.

5.2 IDENTIFICATION OF MAPPING CONCERNS

On 31st May 2022, an external provider raised concerns with the Acting Manager, Children's Audiology Service about the mapping of CI for four children[55,56] who had transferred their audiology care from the South Australian Paediatric Cochlear Implant Program at the WCHN to the external provider. The suggestion by this provider was that these children did not have satisfactory access to sound because the mapping of their implants was incorrect[57].

5.2.1 INITIAL RESPONSE

The WCHN commenced an investigation once these concerns were brought to their attention. This initial investigation included:

- A case note audit for each of the children that occurred throughout June and July 2022.
- A meeting between the WCHN and the external provider to better understand the clinical concerns.
- 'Open disclosure' discussions with the families of the identified children.

Concerns regarding this sentinel cohort were raised to the level of the Executive Director, Allied Health (WCHN) who is the executive responsible for the Paediatric CI Program and the Safety and Quality lead for Allied Health (WCHN) in early June 2022. The WCHN then became aware of a further child on 28 July 2022[58]. A cluster incident was recognised and documented on 4 August 2022[59].

The Children's Audiology Service CI Risk Discussions commenced[60] and the WCHN identified that:

- A system problem had likely occurred and there was a need to review procedures, particularly the post implant procedure.
- The need for formal training for the Paediatric CI audiologists.
- There was not a standardised approach to CI care following implantation
  - Appointments for mapping following cochlear implantation were not occurring frequently enough.

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[55] Five children had transferred their care to the external provider between November 2021 and June 2022.

[56] Incident reports were completed for each child on or around 2 June 2022. Each incident was rated as a SAC 3. Effective from 1 July 22, the Safety Assessment Code (SAC) rating system for patient incidents is replaced by the Incident Severity Rating (ISR). In accordance with the Patient Incident Management and Open Disclosure at the WCHN, all investigations of ISR 3 incidents should be completed within 30 days.

[57] The reported trend was that the T (threshold levels) had been set where the original C (comfort levels) were set.

[58] SLS completed 25th August 2022.

[59] Cochlear Implant Risk Discussion notes 4 August 2022.

[60] CI Risk Discussions commenced on or around the 28 July 2022.

  - There was no formal pathway to investigate the link between access to sound and children who had delayed development.
- A system risk assessment to identify gaps in the service was identified as a required action[61]
- In addition, the WCHN proposed to review the scope of specialist services provided by the Paediatric CI Program and identify the timing of transfer to external providers for ongoing audiology services[62]. There was acknowledgement that there may be a need to review resources to ensure that capacity to sufficiently service the CI caseload.
- The development of a communication plan[63].

The WCHN put in place mitigation strategies whilst it assessed the scale of the mapping concerns. These included:

- A recommendation that the map settings be forwarded to the manufacturer for review, if prior to any CI appointment to review the previous map, the Paediatric CI audiologist determined that the setting was outside the population mean.
- De-identified records were forwarded to two interstate public Paediatric CI Programs (26 August 2022) to obtain feedback on the map setting and the management provided to these children by the CI audiologists within the Paediatric CI Program.
  - External feedback was received on 5 September 2022. This identified that the maps provided by the WCHN had not been set accurately to ensure that the children had satisfactory access to sound[64].
- Arrangement for staff to undertake basic skill training (CI basic skills).

In addition, the WCHN identified that several rectification strategies needed to occur in the interim:

- Exploration of formal training and support opportunities with other Paediatric CI Programs.
- Development of a Paediatric CI procedures particularly the post cochlear implantation. procedure.
- Review of the skills and knowledge matrix for the Paediatric CI audiologists.
- Review of the behavioural assessment.

The ERT was concerned about the adequacy of this initial response. Firstly, it took over two months for these events to be defined as a cluster incident despite being notified of mapping issues with four children. The WCHN appeared to have placed a heavy reliance on identifying five patients to reach the threshold for a cluster[65] rather than examining the

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[61] Briefing document to the Office of the Minister for Health and Wellbeing (MHW-H22-5655).

[62] Briefing document to the Office of the Minister for Health and Wellbeing (MHW-H22-5655).

[63] This has never been provided to the ERT.

[64] Feedback from the two public paediatric cochlear implant programs.

[65] The South Australian Patient incident management and open disclosure policy directive Version V2.3, Approval Date, 15/5/2020.

risk that was present. Much of what occurred in late July 2022 should have occurred earlier.

The mitigation strategies were to manage the current risk and were considered by the ERT as interim measures whilst the size of the problem was identified. The ERT was surprised about the reliance on checking of the map setting with the manufacturers. Whilst the manufacturers are considered experts, their expertise is in their devices. The ERT would have expected that the existing Paediatric CI audiologists at the WCHN would have recognised the nature and the extent of the issues in the four sentinel children once the cases were brought to their attention. The fact that they did not identify the issues earlier is concerning and highlights either:

- A poor review process in the first two months including that the case notes were simply not reviewed by the WCHN over this period which would seem unlikely and / or
- None of the CI audiologists possessed the appropriate skills to accurately undertake paediatric CI mapping in young children less than 5 years of age.

Finally, not all the rectification strategies have been achieved during the last 12 months.

- The post cochlear implantation procedure was not updated during this time[66].
- The skills and knowledge matrix was not reviewed at this time, nor was there evidence that the current staff had completed the CI skills and knowledge matrix[67].

5.2.2 CLUSTER INCIDENT

A cluster incident is an adverse incident where there is a group or series of harmful incidents that are the result of one systemic error or issue and that involves a systems failure or multiple system failures that does or has the potential to compromise the safety of more than five patients68. Both the South Australian Patient Incident Management and Open Disclosure Policy Directive[69] (Statewide Policy Directive) and the Patient Incident and Open Disclosure at the WCHN Corporate Procedure[70] (the WCHN Procedure) give specific guidance on how to investigate, escalate and conduct incident management when a cluster has occurred. The Statewide Policy Directive[71] provides guiding principles for the level of escalation of significant patient events specifically details the requirements for a cluster incident to include:

- Written report required to the LHN CEO.

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[66] The ERT has been informed that this procedure has been completed July 2023 and is now being peer reviewed.

[67] Completed knowledge and skills matrix for two staff were provided to the ERT after initial observations / feedback from the ERT to WCHN.

[68] The South Australian Patient incident management and open disclosure policy directive Version V2.3, Approval Date, 15/5/2020, p 26.

[69] South Australian Patient incident management and open disclosure policy directive, VersionV2.3, (15 October 2020).

[70] Patient Incident and Open Disclosure at the WCHN Corporate Procedure (3 October 2019), with a version update on cluster events endorsed on 11 November 2020.

[71] South Australian Patient incident management and open disclosure policy directive, VersionV2.3, (15 October 2020). S 3.9.

- The CEO of the LHN is required in writing to notify the SA Health Deputy Chief Executive using a Clinical Incident Briefing (CIB).
- If the patient incident was a system failure or error and more than one patient has suffered actual harm or potential for future harmful outcome (cluster incidents with harm) and a lookback review is required to determine the scope and the numbers of patients affected and to provide a coordinated response.

The WCHN Procedure reflects all these escalation requirements and includes a third as detailed below:

- Briefing the CEO of the LHN or state-wide service within 24 hours.
- Undertaking a review using a lookback methodology.
- Notification and clinical analysis of cluster incident to be tabled at the Significant Event Review Committee (SERC)[72].

The declaration of a cluster incident triggered a lookback review[73] however, did not trigger the expected structured approach to the management of the concerns. Neither the Statewide Policy Directive nor the WCHN Procedure give clear detail around how the incident should be managed as far as an ISR rating. During the consultations for this governance review, it became clear to the ERT that some senior staff at the WCHN believed that a cluster event should have triggered a Level 1 response to the incident. This would then have led to earlier involvement of the WCHN Safety and Quality Unit.

Recommendations

33. In small programs, such as the Paediatric Cochlear Implant Program, that the definition of what number of incidents constitutes a cluster be reduced to less than five cases. A cluster needs to be considered when three cases of concern are identified or where there is an observable trend. To identify these trends, it is essential that Key Performance Indicators are in place that can be monitored and reported on regularly.

34. That when a cluster is notified the escalation process involves the safety and quality team to support the lookback, investigation of root causes and the open disclosure process with clearly defined methodologies.

5.2.3 LOOKBACK REVIEW

A lookback review process[74] involves

- Identifying tracing, communicating, and providing appropriate ongoing advice to and/or management of the group of patients.

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[72] Patient Incident and Open Disclosure at the WCHN Corporate Procedure (3 October 2019), with a version update on cluster events endorsed on 11 November 2020. S. 4.

[73] Patient Incident and Open Disclosure at the WCHN Corporate Procedure (3 October 2019), with a version update on cluster events endorsed on 11 November 2020.

[74] SA Health, Lookback Review Policy Directive, V 1.0 (14/07/2016)

- Notification to appropriate external bodies, senior management and executives of the health service and the Department for Health and Wellbeing.
- Establishment and implementation of a coordinated plan for review, investigation, and determining recommended actions to prevent recurrence[75].
- Formation of a communication strategy, including notification to the wider public where appropriate.

The Lookback Review Policy Directive has not been reviewed since the devolved governance structure for health came into effect in 2019. The ERT was told that this directive is currently under review by the DHW but in absence of a local policy the principles of this directive should apply to any lookback review.

Compliance with the Lookback Review Policy Directive is mandatory. It includes the formation of a steering group[76] and an expert advisory group[77]. Action plans must be developed that include responsibility for the identification and tracking of affected patients and providing reports to the DHW and to the LHN Clinical Governance Committee (or equivalent). The Lookback Review Policy Directive also requires the LHN to ensure sufficient resources are allocated for the investigation. The Lookback Review Policy Directive is silent on the methodology to be employed for the review.

The ERT acknowledges that the WCHN undertook pockets of work when the concerns were identified. However, for the most part this work was reactive rather than systematically planned. Throughout much of the documentation provided to the ERT, it was evident that tasks were assigned to individuals, many with identified completion dates however, it was rare that these completion dates were met. The WCHN:

- Identified that a lookback review was the process to be applied, however there was no governance framework around the process including the meeting of timelines for each action.
- No steering committee or expert advisory group was established to oversee the lookback review to guide / determine the methodology chosen for the lookback. Methodology of the lookback was determined by the WCHN. Please refer to Section 5.2.4 for details on the methodology.
- This cluster incident had a very localised focus rather than taking an all of organisation approach.
- The lookback review was disconnected from the quality and safety systems at the WCHN. The lookback review process indicates that the Director of Clinical Governance / Safety, Quality and Risk needs to be involved. There was no evidence provided to the ERT that this occurred. The staff member responsible for Safety and Quality Allied Health at the WCHN attended some of the CI Risk Discussion meetings

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[75] The Lookback Review Policy Directive is silent on the methodology to be used for the review - each LHN is given the licence to decide on the process to be employed.

[76] Membership should include a member of the Health Service Executive and the Director of Clinical Governance / Safety, Quality and Risk, a local media and communications branch delegate. A delegate from the Department of Health and Wellbeing may be allocated to work with the LHN at all stages of the review.

[77] Membership should include experts in the clinical area of concern.

however in general, the Safety and Quality Unit were kept at arm's length from the review, as it was very much managed at a department level. The WCHN missed the opportunity to get support from the Safety and Quality Unit and the Executive Director of Medical Services, who is also the Chair of the SERC. The incumbent was not aware of what the service was doing to investigate the extent of the issue nor what processes were put in place to mitigate any future risks of similar events occurring and whether these were appropriate or not. During consultations, the ERT was told that the Safety and Quality Unit regretted that it had not 'pushed harder' to be involved in the lookback review.

- Notification and clinical analysis of a cluster incident must be tabled at the SERC[78]. Of significant concern to the ERT was that this only occurred in July 23, 12 months after the initial concerns were raised. Whilst the lookback review process is silent on specific timeframes, this was an unacceptably lengthy period and further demonstrates how disconnected the Safety and Quality Unit at the WCHN were from the management of these concerns.
- Whilst there were regular CI Risk Discussions, they were mainly attended by the Paediatric CI staff who were allocated tasks in addition to their regular workload. Whilst these risk discussions were documented there was not, until recently, a plan with accountability and timelines of when actions were expected to be completed. As a result, evidence of completion of the many changes deemed necessary, was not available as of June 2023
    - Procedures remained in draft form for months including a procedure that describes post cochlear implantation processes (including mapping).
    - Gaps in education and training that were identified in late July 22 were not addressed satisfactorily and in a planned and individual way for the audiologists.
    - None of the audiologists had a completed WCHN audiology knowledge and skills matrix until June 23.
- The WCHN was responsible to ensure that there were adequate resources available to undertake the review. The review was a mammoth task for the audiology staff, who continued with their own workloads throughout the review period. This placed an unacceptable burden of responsibility on an already stretched clinical service.

A cluster incident mandates a lookback process but when this revealed the extent of the mapping issues, the ERT had concerns that there was no robust consideration as to why the incidents occurred (the underlying root causes, system issues, capacity, and capability issues). These were all lost opportunities. This may have occurred if the initial findings had been tabled at the SERC. The ERT were left with the impression that the team at the WCHN failed to adequately comprehend the many systemic issues that may have led to the incidents occurring but rather maintained a much narrower focus.

In line with the above, one of the key observations of the ERT was that during the lookback review, the WCHN may have prematurely concluded that one or potentially two individuals were strongly associated with the mapping concerns. As a result, the focus on determining whether potential systemic issues were the root cause, lost momentum. It appeared to the ERT that the WCHN team may have concluded that the root cause of the problem 'had

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[78] Patient Incident Management and Open Disclosure at the WCHN, sp2019_017, Approved 3 October 2019.

been identified' and to some extent eliminated. This reasoning was revisited several times during this governance review. It seems that the process of a system wide review was never prioritised because the WCHN had 'found the cause' and moved on.

Recommendations

35 The Women's and Children's Health Network update its *Patient incident management and Open Disclosure at the WCHN* procedure to align with the *South Australian Lookback Review Policy Directive*. This update will include, but not be limited to, clear requirements for leadership from the Chair of the Significant Events Review Committee (Executive Director of Medical Service), formal oversight through the Executive Clinical Governance Committee and reporting requirements to the Board Clinical Governance Sub-committee.

36. The Women's and Children's Health Network ensure that all cluster incidents are managed using formal critical incident review methodology with clearly identified recommendations that include person/persons responsible with a delivery date. These must be monitored through the appropriate governance committee to ensure the actions are completed.

5.2.4 CLINICAL REVIEW PROCESS FOLLOWING IDENTIFICATION OF THE ISSUES

The Statewide Policy Directive[79] states that the appropriate methodology for a cluster incident is a lookback review, initially to assess the scope and number of patients affected and then to coordinate the appropriate response to the concerns. One of the concerns for the ERT, as already identified, was the time that it took to identify that a cluster incident had occurred. The timeline suggests that the mapping issues were identified in four children on or around 31st May 2022 – this is evidence that incident forms were completed for these children at that time[80].

The lookback undertaken by the WCHN involved two phases. Initially only children actively in the Paediatric CI Program as of July 2022 were identified for review (Phase 1). It was later determined that the review would include children who had transferred from the program and were not active patients of the WCHN but had been involved in the program between January 2006 and July 2022 (Phase 2). Children who were over 18 were not contacted or included in the lookback review.

The protocol, scope and methodology for the lookback review was developed by the Paediatric CI team. It was reported to the ERT that advice from CI manufacturers, Cochlear and MED-EL, was used to inform elements of the lookback protocol.

Both Phase 1 and Phase 2 of the lookback were undertaken by the WCHN Audiology Team and findings recorded in an excel spreadsheet (CI Risk Management database)[81]. Protocol for the lookback included CI device parameters, aided detection, behavioural observation audiometry and Ling sound detection. Device parameters included reference to

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[79] South Australian Policy Directive Patient Incident Management and Open Disclosure Policy Directive, VersionV2.3, Approval Date 15/5/2020, p. 20.

[80] South Australia Health Incident / Event / Investigation / Review Forms were provided for each of these children.

[81] CI Risk Management database 28/06/23.

optimised T and C levels, relationship between C levels and neural response telemetry (NRT) for Cochlear devices and MCL units and thresholds for MED-EL devices. The CI risk management database included additional definitions of concern and elements that were not detailed in the protocol. The lack of alignment between the protocol and documented outcomes in the CI risk management database raises concerns over the accuracy and consistency of the lookback undertaken.

The CI risk management database suggested that 157 patient electronic mapping files were sent to CI manufacturers for review. The outcome of the manufacturer review was not documented in the database, and it remained unclear to the ERT if and how the outcome of manufacturer review was used to inform categories of concern.

The protocol, scope and methodology for the lookback defined categories of concern based on aided results with no reference to CI device parameters or Ling detection[82]. It is of concern that the lookback review did not take into consideration functional performance and raised the possibility that not all children of concern have been captured by the applied review. As a result of these observations the ERT has seen evidence that measures have been put in place to offer an external clinical review of all children in the Paediatric CI Program commencing late July 2023.

External review of 5 cases was sought from paediatric CI teams in WA and QLD on 26 August 2022. Written communication on 5 September 2022 from WA and QLD noted significant concerns with the approach and clinical decision making for the 5 children (Folder 39 Clinical records –Docs from third party identify risks – Perth CI summary comments and Adelaide case reviews PDFS)

The 5 cases reviewed by external CI teams in QLD and WA were also reviewed by the ERT. The ERT made observations consistent with the teams in QLD and WA. There was good evidence the application of mapping strategies to improve sound detection following concerns with sound detection being noted in the clinical record, reported by external providers and/or parents, were ineffective. This suggested a lack of knowledge of the principles of mapping by some audiologists at the WCHN.

5.2.5 ESCALATION TO THE WOMEN'S AND CHILDRENS HEALTH NETWORK

In any speciality unit, there is an assumed trust in the relationships between the clinical leads or managers and the Executive to whom they report, around the quality of the clinical care provided. The assumption is that care meets a minimum standard and that any concerns to the contrary are quickly identified and reported. The Paediatric CI team had previously identified workforce concerns and there had been some tension in the relationship with another external provider, however the full extent of these were not fully uncovered during this review.

The lookback review was done at a local level and appeared to bypass the normal pathway through which an aggregate review incident would have been investigated. As a result, the ERT was left with the impression that much of the escalation occurred in local huddles with actions assigned to staff within the Paediatric CI program that were already overstretched from a clinical and resource perspective. As a result, there was a distinct lack of a

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[82] WCH Review – Task Protocol scope and methodology.

systematic approach to ensuring all recommendations were completed in a timely manner. A key focus remained on identifying children "of concern" throughout the initial phases of the investigation.

The WCHN CEO was alerted to the mapping concerns in early August 2022 once the cluster had been confirmed by the Allied Health Executive Lead. The CEO made the then WCHN Board Chair aware of the concerns in the Paediatric CI Program in August / September 2022 but at that stage no formal documentation or report was presented to the full Board because the WCHN did not know the extent of the issue.

The ERT was told that at the 6 October 2022 meeting the Board received an in-camera briefing[83]. The ERT was told that the incident data provided to the Board Clinical Governance Sub-committee at the November meeting[84], had s single line which referenced a child being reviewed by the Paediatric CI Program and as such did not raise any flags for the Board Clinical Governance Sub-committee. The Board were subsequently provided with an update on 6 April 2023 from the Chief Operating Officer and ENT surgeon[85] and provided with a further update on 6 July 2023 by the Allied Health Executive Lead[86]. The ERT was also told that the Board was being kept updated between scheduled meetings and that on commencement in February 2023 the incoming Board chair was briefed on the issue.

The ERT was told that Board members felt re-assured following briefings. They felt that they were seeing progress, understood what was occurring with the clinical reviews and that strategies were in place to check the mapping. The Board reported feeling confident in the audiology department given the current scrutiny and checks as well as the relationship with Cochlear Ltd to check the mapping. The challenge for Board's is whilst a collaborative relationship with the executive team and trust is important a balance must be maintained in ensuring this relationship allows for free and frank exchanges that allow the Board to maintain their independence ensuring they are able to fulfill their fiduciary duties. Board culture is an increasing focus of effective governance and organisational performance.

The ERT team recognise the current governance structure that exists in SA in relation to reporting of significant clinical incident and would have expected that the Board, because it holds responsibility for LHN matters, would be briefed throughout this period in a formal manner given the nature of the incidents that were identified and how these were escalated. There may have been a sense that these concerns had been escalated to the highest level. However very early on these issues had the very real potential for media scrutiny, as subsequently occurred in 2023 and the Board should have had more oversight of the matter at an earlier stage.

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[83] At later briefings some board members could not recall the briefing.

[84] Incident report dated November 2022.

[85] https://cdn.wchn.sa.gov.au/downloads/WCHN/about/governing-board/meeting-agendas/WCHN-Governing-Board-Agenda-6-April-2023.pdf.

[86] https://cdn.wchn.sa.gov.au/downloads/WCHN/about/governing-board/meeting-agendas/WCHN-Governing-Board-Agenda-6-July-2023.pdf.

Recommendation

37. The Women's and Children's Health Network review its process for information sharing, related to significant / events to the Board and the Board Clinical Governance Sub-committee.

5.2.6 ESCALATION TO THE DEPARTMENT FOR HEALTH AND WELLBEING

In late July 2022 the complaints had reached AudA and the Health and Community Services Complaints Commissioner[87]. The Office of the Minister for Health and Wellbeing became formally aware in early August 2022 when it was notified by the external provider and the DHW in September 2022. Information sharing of the progress of the initial internal review with the DHW, and the Office of the Minister was primarily through briefs. The ERT understand that a verbal brief was provided by the WCHN CEO and Board Chair at their regular meeting with the Minister on 25 August 2022.

An initial brief was prepared for the Office of the Minister for Health and Wellbeing on 13 September 2022 providing a summary of actions undertaken by the WCHN in response to concerns raised by the external provider in its written communication to the Minister (5 August 2022). This brief does not mention that on 4 August 2022 a fifth child was identified with mapping issues, nor does it mention that this was when WCHN first declared this a cluster event. There was no evidence of discussion with the DHW for any direction to follow the Lookback Review Policy Directive in establishing a steering group with a relevant DHW delegate allocated to work with Health service at all stages of the lookback.

The WCHN provided the DHW updates in the form of Ministerial briefs. These occurred in relation to work being undertaken and in response to specific issues and concerns raised by parents and other interested parties. The briefs did not include any evidence, detailed action plans or reports to support what was documented in the briefs. The DHW relied heavily on what they were told about the progress of the incident review. As the system leader, the DHW oversees, monitors, and promotes improvements in the safety and quality of health services[88]. There is a dedicated Safety and Quality Unit within the DHW that works in partnership with health services and consumers to improve patient safety and quality of care. This unit oversees the reporting and investigation outcomes of clinical incidents and is responsible for the statewide safety and quality policies. The ERT was told that the safety and quality unit had not been involved in supporting WCHN in the lookback process or any aspect of managing this issue.

Recommendation

38. The Department for Health and Wellbeing review their role in the management of significant incidents including clusters particularly around oversight and management.

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[87] CI Risk Discussion dated 28 July 2022.

[88] Changes to the Health System Governance, role of the Department of Health and Well-being, August 2021.

5.3 COMMUNICATION WITH FAMILIES

5.3.1 WHAT THE ERT HEARD FROM FAMILIES

As part of this review families were invited to make submissions either through a response to the public request for submissions or after being formally contacted[89], via registered mail, by the ERT. There were some very concerning comments made by the families and there was consistency amongst many of the experiences reported by the families.

In interviews with parents, the ERT learnt that parents had frequently raised concerns, usually related to their child's hearing ability, with the CI audiologists at the WCHN but that these were often dismissed by the CI audiologists as:

"… your child needs to wear the processor more"

"[your child is] 'just a bit slow"

"just give him more time [with the implant]"

"[as a parent] you need to do more"

"I remember constantly leaving those appointments not feeling heard"

"… are you doing the homework I gave you to use at home … I felt so judged, like I wasn't doing enough, like I was the reason my child was so behind"

"… my heart breaks almost every day, seeing my child be left out of interactions with other children because she couldn't respond or be as involved as she could be"

Parents told the ERT that they were made to feel that it was their fault that their child could not hear or were not progressing as expected. One parent summed this up and described it as feeling judged that she personally was not doing enough with her child, and that was why he was failing to catch up to where he was supposed to be.

Parents reported being "fobbed off and ignored when they raised concerns about progress including after they reported specific details of their child not responding to loud sounds and lack of progress with speech. One parent describes her experience with the WCHN as

"I honestly felt like I was treated like an uneducated idiot by the Women's and Children's Hospital and not just by the audiology department"

One parent describes her experience, her child was not progressing as she would have expected including not even making sounds and not really acknowledging her family. Instead of listening to this parent she was told

"… you need to do more, it will click for her soon, be patient, make sure she wears them [CIs] more"

This parent reported that every time she mentioned that perhaps the implants "weren't working" this was met with silence. This child has had significant change made to their maps following the concerns, however the parents believe that due to the under mapping

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[89] Not all current contact details were available to the ERT as some children had transferred out of the service, relocated or were > 18 years. The ERT contacted the families of as many children as possible during the review process given the timelines available.

their child's life will be significantly impacted. The mother also discussed about how their family's life was impacted and the toll that it had taken on her own personal health. Many parents discussed the broader impacts of the under-mapping on their family life.

Parents consistently told the ERT that "no one listened" and they felt they had to accept what they were being told as the professionals are supposed to be the experts. Some reported this experience both at the WCHN and at external providers. Families also reported that they were not taught how to care for the technology. Another parent describes how her son at 12 months was non-verbal and wasn't turning to any sounds despite having HAs. She explained how it took a further 12 months for someone to listen to her, only to then discover that her instincts were correct. This child was then offered and fitted with CIs.

The impact of the under mapping, the late fitting and the poor management of families will be lifelong for many of these children and will likely impact on social, education and employment opportunities. The impact of the under mapping will also be lifelong for many of the families with one family describing this as:

> *"… every choice we make is now coloured by their child's special needs which if the mapping had been done correctly, we would be able to lead a relatively 'normal' life – that choice has been taken away from us"*

Families put faith in the professionals and firmly believed that the care their children were receiving was the best available and appropriate. The impact of this is described by one parent as:

> *"… to say I'm angry is an understatement. I'm angry, frustrated, sad, confused, and disappointed"*

Several parents commented that until these issues were raised, they were not aware that they had options to receive care elsewhere. Others commented that they had requested a move to another service, but this was met with resistance from the WCHN.

The WCHN Clinical Governance Framework[90] describes the importance of the relationship between health providers and consumers as "Effective consumer partnerships are essential for improving healthcare outcomes and driving continuous improvement. Listening and responding to the consumer voice is at the origin of good clinical governance". Listening to feedback and a willingness to investigate concerns and complaints are key to improving outcomes and quality of care. The ERT found no evidence of systems focused on striving for clinical excellence in the management of patient and carer concerns and complaints within the Paediatric CI Program.

Leaders are responsible for ensuring patient and carer concerns are acted upon. Listening to patients and their carers requires leadership and a culture that is open to feedback and willing to investigate complaints and concerns to improve outcomes and quality of care. The expectation is that these would be led by the Children's Audiology Service with appropriate oversight and supervision of the relevant Executive Director.

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[90] WCHN Clinical Governance Framework, v2.1 February 2021

Recommendations

39. The Paediatric Cochlear Implant Program ensure that patients and their families are genuine active partners in their healthcare and that they have a formal experience of care and suggestions for improvement feedback mechanism in place.

40. That the Paediatric Cochlear Implant Program prioritise work that will enable patients and their families to be genuine active partners in their healthcare.

5.3.2 WOMEN'S CHILDREN'S HEALTH NETWORK CORRESPONDANCE TO FAMILIES

Following the recognition that a cluster incident had occurred, families of children who were actively involved in the Paediatric CI Program (n = 117) were contacted by the WCHN[91]. This occurred through a series of text messages and letters to advise firstly that the WCHN had been made aware that an issue had occurred with the mapping in some children who were part of the Paediatric CI Program. A communication timetable is found at Appendix 5

A general letter identifying the concerns was forwarded to all Phase 1 families in September 2022. The sentinel children identified were not included in these initial mailouts and did not receive any communication from the WCHN for over 12 months.

> "*... when we were recently notified that a small number of children had incorrect implant settings. We commenced the review of all children's settings. This review is now underway and is being conducted at an abundance of caution. We will check your child settings as usual at your next appointment and the team will contact you directly should your child need to come in for an earlier review"*

Further letters were forwarded in October alerting families about the level of concern for each child. The letters sent on 19 October 2022 to families / carers of children who were identified as being 'of concern' in the initial review of clinical notes provided them with the following information:

> *"Further to the letter you received in September 2022, the Women's and Children's Health Network Audiology Department have been undertaking an extensive review of all the maps of children and young people in the Cochlear Implant Program. As a result of this review, we will require a follow up appointment for your child in order to ensure the accuracy of their MAP. Your child has been scheduled for a priority review appointment as per the appointment letter enclosed"*

When speaking to parents during the review it was evident that they felt that the impact of the under mapping had been underplayed by the WCHN. One parent ignored the letter because she felt that it did not apply to her family as her child was not a baby. It was only months later, into 2023, that she became aware that the impact was across all ages, and she then received a second opinion for her child. Not all parents understood the urgency nor the implications of attending this appointment. In retrospect parents believed that they should have been informed more fully about the mapping concerns much earlier.

Children deemed 'not of concern' in the Phase 1 group were asked to attend at their usual appointment.

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[91] Children in Phase 1 of the review by WCHN

> *"As a result of this review. We can advise that your child's map was not highlighted to be of concern. Your child has been scheduled for their standard review appointment as per the appointment letter enclosed"*

One parent told the ERT that she understood this to mean that there was nothing to worry about. At her routine appointment which was some months later concerns about the mapping were identified. This reinforces and highlights that the process used during the review was not necessarily sensitive enough to identify all children 'of concern' and alternatively some of the children identified as being 'of concern' where subsequently found to be 'not of concern'.

In March 2023, the WHCN wrote again to the families providing an update. This included that the WHCN has been working with families who were actively part of the Paediatric CI Program to check and update the CI maps.

When the scale of the mapping concerns was identified the WCHN made the decision to review all the children who had been part of the Paediatric CI Program since 2006 (Phase 2 children). It was decided that children who were now 18 years would not be included in this process. As a result of this decision this older cohort, now young adults, were never contacted to inform them of any of the mapping concerns.

Finally, in May 2023 families were contacted by letter, to inform them for the first time, about the scale of the issue. This is some 12 months after the concerns were first identified.

> "*The program has undertaken clinical reviews of children currently within the service and, if required, the maps have been adjusted for these children to allow for optimal performance of the cochlear implant.*
>
> *During this first phase of our review, we identified that of the 117 children currently in our program, approximately 30 had had potential issues with implant mapping. This means that while these children were able to hear through the implant, it is possible that they may not have been hearing at the optimal level for their specific condition.*
>
> *We have now commenced a further clinical review of all children that have been associated with the program since 2006 and are currently aged under 18, but who have since left the program"*

Information was also formally provided about alternate service providers in this communication for the first time.

> *"Should you decide to pursue care for your child, outside of WCHN, you should feel safe in the knowledge that the transfer of care will be facilitated by WCHN, at your request, when it is appropriate to do so, and this will not affect your ability to receive care at WCHN in the future if required"*

Some parents provided feedback to the ERT about their level of dissatisfaction as it still implied control over their care with the words 'when it is appropriate to do so'.

5.3.3 OPEN DISCLOSURE

The Australian Commission on Safety and Quality in Health Care (ACSQHC) define open disclosure as the '*open discussion of adverse events that result in harm to a patient whilst receiving care with the patient, their families and care givers*'. Open disclosure (OD) includes an **apology** and **explanation** of the incident without apportioning blame. Patients and/or families are given information about what happened in a timely, open, and honest manner.

Open Disclosure is a component of the Clinical Governance Standard in the National Safety and Quality Health Service (NSQHS) Standards. Therefore, all health services are **required** to provide open disclosure discussions when 'something goes wrong'. Essential to the provision of OD is training for staff so that they ensure that support is provided during the process to both the patients and to staff who participate in the process. The Australian Open Disclosure Framework[92] provides a nationally consistent basis for communicating following unexpected healthcare outcomes and harm.

The South Australian Patient Incident Management and Open Disclosure Policy Directive 2020[93] references this national framework[94] as does the corresponding WCHN procedure[95]. The level of open disclosure required because of an incident is outlined in both the Statewide Policy Directive and the WCHN Procedure with the level of open disclosure depending on the outcome and circumstances of the incident. The WHCN initially classified these individual mapping incidents with either an Incident Severity Rating (ISR) of 3 or 4. These incidents are when there is

- No permanent injury.
- No increased level of care required (e.g., no transfer to operating theatre or intensive care unit.
- No, or minor, psychological, or emotional distress.

According to both the Policy Directive[96] and the WCHN Procedure[97] such incidents require a Level 2 OD response[98]. This policy directive goes on to state that a Level 2 OD response can '*occur at or near the time that the incident is identified but should be completed within*

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[92] Australian Commission on Safety and Quality in Health Care (ACSQHC), The Australian Open Disclosure Framework, 2013, p. 8.

[93] Patient incident management and open disclosure Policy Directive, V2.3, (15 May 2020).

[94] It is understood that this policy directive is currently under review to ensure it better aligns with the ACSQHC framework.

[95] Patient Incident and Open Disclosure at the WCHN Corporate Procedure (3 October 2019), with a version update on cluster events endorsed on 11 November 2020.

[96] Patient incident management and open disclosure Policy Directive, V2.3, (15 May 2020).

[97] Patient Incident and Open Disclosure at the WCHN Corporate Procedure (3 October 2019), with a version update on cluster events endorsed on 11 November 2020.

[98] This response does not require a team of staff and can be conducted by the patient incident manager or senior member of the patient's clinical team.

24 hours if practicable. The process and the outcome should then be documented in the SLS in the managers section of the incident'[99].

5.3.3.1 Open Disclosure Process for Initial 5 children

The documentation provided to the ERT indicates that OD for the initial five children was conducted by telephone by the WCHN CI Clinical Lead audiologist. These discussions occurred between 5 July 2022 and 3 August 2022.

The documentation reviewed by the ERT confirms that these conversations complied with the expectation of a Level 2 response as described in the WCHN procedure[100]. At the time these OD discussions were conducted, a cluster had not been officially identified. The documentation contains evidence of an overview of the discussions, an expression of regret and a commitment to keep the parent/care giver informed of the outcomes of steps being taken to prevent reoccurrence. All except for one record documents a verbal confirmation of the accuracy of the discussion.

Parents interviewed by the ERT who had open disclosure conducted by telephone stated they did not understand and were unaware that this was an OD conversation. This included those who are familiar with what would constitute an OD process. The WCHN has made no further contact with any of these five families to offer any other information about these events despite informing the families, and documented same in clinical notes, that it would do so.

5.3.4 OPEN DISCLOSURE IN THE EVENT OF A CLUSTER

The WHCN did not identify that this was a cluster event until at or around the 4 August 2022. The Statewide Policy Directive[101] states that a **cluster** event requires a Level 1(**high-level response)** that includes, amongst other requirements, the following:

- An Open Disclosure Facilitator **must** be present or lead the process.
- The senior treating clinician to be present.
- The nomination of a contact person who is not part of the treating team for the patient, and family/carer.
- A consumer advocate or equivalent support person if requested.
- The Safety, Quality and Risk Manager may provide advice.

The important element here is the reclassification of the required response to be aligned to an ISR 1 or 2 incident.

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[99] South Australian Patient Incident Management and Open Disclosure Policy Directive, 2020, p. 12.

[100] Patient Incident Management and Open Disclosure at the WCHN, sp2019_017, (3 October 2019).

[101] South Australian Patient incident management and open disclosure policy directive, VersionV2.3, (15 October 2020), Section 3.4.2.

The WCHN Procedure[102] does not provide any further detail of the requirement for or the process of OD in relation to families in the event of a cluster incident. This procedure indicates that WCHN staff are expected to comply with the requirements of the Statewide Policy Directive[103]. The ERT consider that the WCHN Procedure is not consistent with the Statewide Policy Directive when there is a reasonable expectation that any policies and processes developed by a LHN will be substantively reflective of any state-wide policy directive, as a result all children involved in the cluster incident have not had satisfactory OD disclosure discussions.

5.3.4.1 Open Disclosure Process for the Identified Children of Concern

Despite the WCHN reporting in April 2023 that it had and will be continuing to provide full OD as required and appropriate to all children under the age of 18 in the program dating back to 2006[104] the ERT did not see any evidence of OD conversations being offered and then conducted with all families when a child was identified as being 'of concern'. Despite several requests the ERT was not provided with this evidence and therefore the number of families that had OD does not align with the numbers of children impacted by under mapping.

The ERT was informed that OD occurred for a further 6 children during the past 12 months. The ERT has seen documentation of OD meetings, that occurred in late March 2023, for some of these children. This included the involvement of WCHN staff (audiologist and two WCHN Executives) consistent with the requirements of a cluster OD discussion as outlined in the Statewide Policy Directive[105]. The ERT has also seen a letter to another family from a senior WCHN staff member which appears to be post an OD meeting however there is no mention of who was present at the initial meeting.

When asked about the OD conversation for this wider group the ERT was told by the WCHN that OD occurred during face-to-face clinical appointments where the results of mapping were discussed including the actions taken to rectify the mapping concerns. Not only is this inconsistent with the requirements of OD in a cluster event, but there are concerns that there is no documentation of these conversations occurring as OD discussions. Parents who were in the situation indicated when interviewed that they were either unaware that this was an OD discussion or that it did not occur.

The ERT requested information about how decisions were made about the process for OD. There does not appear to have been a planned and criteria-based approach to the provision of formal OD. The ERT remains concerned about the criteria used to determine what families have been provided with formal OD conversations.

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[102] WHCN Patient Incident and Open Disclosure Corporate Procedure dated 3 October 2019, with a version update on cluster events endorsed on 11/11/2020

[103] refer WHCN Patient Incident and Open Disclosure Corporate Procedure dated 3 October 2019, with a version update on cluster events endorsed on 11/11/2020), Section 10.

[104] Communication with Deafness Forum Australia

[105] WHCN Patient Incident and Open Disclosure Corporate Procedure dated 3 October 2019, with a version update on cluster events endorsed on 11/11/2020), Section 3.4.2.

5.3.5 OPEN DISCLOSURE TRAINING

In 2019 South Australia moved to a devolved governance model with delegation of responsibility and costs for OD training and education moving to the LHNs. The WCHN training procedure[106] identifies that OD training is required for all clinical staff at a minimum on commencement of employment[107]. The ERT was told no formal OD training has occurred at WHCN since 2019 when the responsibility for training was transferred to the LHN as part of the move to a devolved governance model.

A briefing document for the SA Health Clinical Governance Community of Practice (CGCoP)[108] states that this training does not meet all the requirements of the Australian Open Disclosure Framework which is the expectation of how health care staff will be trained to provide OD to patients and their families. The briefing recommended that the CGCoP support the introduction of an updated statewide OD eLearn module that meets the requirements of the National Framework. The CGCoP has also been provided with costs for more intense training for different levels of staff.

The WCHN in their regular safety and quality report for the DWH[109] indicated that it had 30 trained facilitators who support OD for all ISR 1 and ISR 2 patient incidents. The WCHN Board has recently approved for 20 staff to undertake in-person OD training.

Recommendations

41. The Women's and Children's Health Network offer open disclosure discussions with the families of all children who were determined to be of concern and subsequently had their maps altered.

42. The Women's and Children's Health Network Patient incident management and Open Disclosure at the WCHN procedure be updated to better reflect the requirements of open disclosure when a cluster event is identified as per the current South Australian Patient Incident Management and Open Disclosure Policy Directive.

43. The Department for Health and Wellbeing progress with the update of the eLearn module for open disclosure to ensure it aligns with the Australian Open Disclosure Framework.

44. That the Women's and Children's Health Network considers:

- Increasing the requirement to undertake the open disclosure eLearn module based on a cascading profile of clinical and leadership roles.
- In person simulation training for those leading open disclosure discussions in ISR1 and 2 and cluster events.

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[106] The WHCN Corporate Procedure – Mandatory Training – Organisation Wide (August 2019)

[107] Training, provided to all SA Health employees, is the Department for Health and Well-Being SLS eLearn module provided at http://digitalmedia.sahealth.sa.gov.au.

[108] South Australia Clinical Governance Community of Practice Briefing Note

[109] Safety and Quality Report for DHW 1/7/22 to 31/3/23

5.4 CHANGES IMPLEMENTED AT THE WCHN

5.4.1 INITIAL CHANGES AT THE WCHN FOLLOWING UNDER-MAPPING CONCERNS

The ERT recognise that work was undertaken at the WCHN since the mapping concerns were first raised at the WCHN in May 2022. The following is an overview of the actions taken by the WCHN and the Paediatric Cochlear Implant Program in the 12 months to May 2023. This section will not detail the OD discussions with families and parents or the lookback review as these have been extensively covered previously in this report but rather this section will detail the actions taken based on the themes that have emerged throughout the lookback discovery and investigation.

5.4.1.1 Policy review and revision

Following the initial discovery process the Paediatric CI team identified that local procedures needed to be reviewed. The two most relevant procedures that were either out of date or remained in draft format.

- The Clinical Procedure: Paediatric Cochlear Implant Mapping[110], remained in draft 12 months after the concerns were identified. The procedure was flagged in September 2022 as being required. An initial draft was developed at this time.
- The Clinical Procedure: Transfer of Paediatric Cochlear Implant Audiology Care to Private Providers. This procedure was in a draft following external provider feedback in 2020.
- Candidacy information was available, but this information was not in a procedure format.

5.4.1.2 Risk Assessment

The WCHN reported to the Office of the Minister for Health and Wellbeing that a systems risk assessment to identify service gaps would be undertaken. No timeframes were given for this assessment. The ERT were provided with a document dated February 2023[111].

The risk assessment identifies several risks including the model of care, access to additional AH disciplines (relationships with external providers, availability of MDT), publicly available information about the Paediatric CI service, and mapping concerns (staff training, competency, supervision). This document identified several actions with dates for completion of relevant actions commencing in June 2023. This included competency assessment and training, procedure completion, development of a monthly performance scorecard. Up until late June 2023, the ERT had not been provided evidence that progress had been made on many of the risks identified in this document except for training. The ERT note that the resources involved in the progression of such an extensive piece of work needs to be supported and the ERT believes that the Paediatric CI team were caught trying to balance their clinical workload with this rectification activity.

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[110] Clinical Procedure: Paediatric Cochlear Implant Mapping (draft 23 September 2022).

[111] Risk Assessment: Governance of the CI Program (February 2023).

5.4.1.3 Review of the scope of the specialist service

The WCHN had certainly identified that the Paediatric CI Program was at its capacity given the workforce available. There were tensions between different clinical groups about how long a child should remain with the specialist tertiary provider, for the mapping of the CI, post implantation. There was certainly a disconnect which the ERT saw firsthand about the timing of transfer of a child to an external provider for ongoing mapping. There appeared to be acceptance that the Paediatric CI Program needs to allow families choice about who their providers are for services, in line with the principles of the NDIS, however the reluctance to allow children to transfer early following implantation remained.

This must be resolved as a matter of urgency as parents report that transferring care on request has remained difficult even into 2023, months after the mapping concerns were identified.

The WHCN report that the Paediatric CI Program has been supported by the WHCN Executive to increase audiology FTE for 6 months to ensure other paediatric audiology services can continue while the WHCN undertake this review[112]. It is unclear to the ERT what and how this increase in FTE was implemented.

5.4.1.4 Professional Development and Training for staff

In one of the early CI Risk Discussions113 the WCHN identified that training of audiologists may have been a concern and a contributing factor to the mapping concerns. A lack of a standardised approach to CI care was noted together with the training that had been provided to the Paediatric CI team in relation to the setting of the map levels[114].

In its response to the concerns, the WCHN indicated that it would develop a competency-based training package for clinicians working in the program. The ERT has not been provided with such a training package. Since the identification of the mapping concerns the Paediatric CI audiologists have concentrated on accessing training both on-site and off-site with cochlear implant suppliers. The ERT has seen evidence of training from both CI implant suppliers in 2023 as well as the willingness, from one provider to provide ongoing audiological support.

- On-line Foundations of Cochlear Nucleus Implant Technology Programming Modules 1 and 2, Cochlear Ltd - two audiologists, total of 20 hours August 2022.
- On-line training in the form of the Med-El CI Bootcamp, Med-El 2022 – total of 8 hours May 22.
- At elbow training with Cochlear manufacturer – 2 weeks December 2022 and a further 6 days in March and April 2023
  - The contract sighted by the ERT indicates that this is to provide audiology support only and there is no requirement for Cochlear team to provide services

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[112] Ministerial Brief 10 November 2022.

[113] CI Risk Discussion 28th July 2022.

[114] Ministerial Brief 13th September 2022.

- At elbow training with MED-EL in 2023[115].
    - Intraoperative measurements training – 2 days (March, May 2023).
    - Fitting parameters and hands on programming – 1 day (April 2023).
    - Advice re the MED-EL implant including processor handling, repairs, troubleshooting and verification of outcomes – 2 days (April 2023).
    - Switch on – 1 day (May 2023).
    - Hands on Mapping verification – 1 day (June 2023).

There has also been engagement and training with interstate Paediatric CI programs. Site visits have already occurred with at least two CI audiologists attending Queensland Children's Hospital for two days each with the purpose of shadowing cases, protocol sharing, pre-implant case study, project work advice and sharing.

Throughout 2022 and 2023 there was significant focus on training and professional development through accessing the CI companies to address any gaps in skills and knowledge in the Paediatric CI audiologists. Education provided by a manufacture would principally focus on the use and application of their device and supporting applications (e.g., mapping software), rather than the clinical skills and decision making required to work effectively with CI recipients. It is not within the remit of CI manufacturers to assess competency or direct clinical decision-making. Small programs can be challenged to reach and then maintain competencies. The ERT observed that the competency testing of the Paediatric CI audiologists was not formally documented. The ERT noted that none of the audiologists had their skills and knowledge matrix completed and signed off during this period. The ERT would have expected that this would have occurred as manufacturer education alone does not address competency or skill in mapping.

5.4.1.5 Communication Plan

A communication plan was to be developed to ensure all families were aware and offered remedial action to ensure their child's hearing assessment was reviewed. The only evidence provided to the ERT was a communication timeline which outlined when letters were forwarded to families. This is no way would meet the expectation of a communication plan. It is noteworthy that the five sentinel families were not sent any further communication between May 2022 and May 2023. In addition, some families felt that the information provided in the letters to them underplayed the significance of the events that occurred and did not prompt them to seek review. One parent was angry with the content of the letters because she felt that the communication from the WCHN did not give her sufficient information to make a sound choice about having her child's maps reviewed.

5.4.1.6 Support for staff

The Paediatric CI audiologists reported to the ERT that they felt supported by management and that they could see improvements since the dedicated Children's' Audiology Manager commenced in February 2023. Collectively the team mentioned support from the Executive Director and the WCHN CEO including how they felt valued and recognised, especially

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[115] Note that only a very small percentage of children have MED-EL implants.

since this has been tangibly demonstrated since the mapping concerns have been publicised.

Staff also reported looking forward to participating in the group Employee Assistance Program (EAP) session as a means of starting to move forward. Individual access to EAP was also reinforced by the Executive Director and CEO.

A Friday review meeting was introduced to allow the Paediatric CI audiologists to discuss cases in an informal way and seek peer support. Whilst they team has not been able to achieve this goal of meeting weekly it demonstrates that they recognise the need and value associated with case discussions and peer support. The barriers to achieving this weekly meeting were reported to the ERT as being staff availability and clinical demands.

5.4.2 CHANGES AS A RESULT OF PRELIMINARY OBSERVATIONS OF THE EXTERNAL REVIEW TEAM

The ERT provided some early observations to the WCHN, the DHW and the Office of the Minister in late June 2023. These observations related to

- the need for all children involved in the program since 2006 to be offered a clinical review
- the need to ensure that all staff were not only provided adequate training in Paediatric CI mapping but that their competency and skills are assessed / validated.

The WCHN responded by providing the ERT with a detailed plan of actions, with accountability, through to the end of January 2024. In addition, supporting evidence to demonstrate progress, agreements and tangible plans were provided. The ERT acknowledges the response from the Paediatric CI Program and the Executive team at the WCHN. Some of these actions will go a long way in addressing the recommendations made in this report.

5.4.2.1 Immediate

- Ensuring the appointment schedule of all children who have received a CI since May 22 was reviewed to ensure it meets best practice guidelines (this has already been completed).
- Finalising the Clinical Procedure: Paediatric Cochlear Implant Mapping[116], and in the process of referring to other Paediatric CI Programs for peer review.
- Collating speech pathology reports for children on the current case load in preparation for the recruitment of a speech pathologist for the Paediatric CI Program.
- Confirmation of the engagement of an interstate provider to commence external clinical review of all children under 18 years (n=158). It was confirmed that the external team will initially be on-site 31 July 2023 – 14 August 2023 with additional time coordinated between the two parties. Children will be offered the clinical review however it could be anticipated that some families have decided to obtain services elsewhere in SA and may not want to take up this offer. Therefore, the number that will be reviewed is not

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[116] Clinical Procedure: Paediatric Cochlear Implant Mapping (draft 23 September 2022).

clear. A detailed document has been provided to the ERT that outlines the work that will be covered by the external provider. This initial body of work will take 3-6 months. The ERT encourages the WCHN to consider offering this service to any child who accessed the Paediatric CI Program since 2006 at a minimum.

- Contract finalised with Queensland Children's Hospital CI Program to provide (under a memorandum of understanding) formal and informal supervision to maintain and develop clinical skills, competency, and knowledge[117]. The hospital has agreed with the WCHN to provide monthly in-house training with staff rotating for the next 12 months up to July 2024.
- There has also been engagement with a clinical expert from Western Australia following identification in gaps of knowledge relating to single sided deafness (SSD). There are plans being developed for the clinical expert to come to the WCHN in August 2023 with the specific purpose of working with the clinical lead on candidacy work-up for SSD, case reviews of current patients and at elbow support for 6 patient's post-implantation.
- Additional education and training organised with the CI manufacturers[118]

5.4.2.2 *Building capacity*

- The WHCN have acknowledged, following discussions with the ERT, that they need to add speech therapy into the Paediatric CI Program team. Recruitment commenced July 2023 for speech therapist dedicated to the Paediatric CI experience.
- Additional audiologist with Paediatric CI experience was targeted – commencing 14 August 2023 (0.6 FTE). In addition, an audiologist is returning from long term leave this year. Both audiologists will be part of the program of support and supervision offered through the Queensland Children's Hospital.
- The Paediatric CI Program to ensure that at least three staff complete competency to provide care to children under 5 years of age. As indicated competency is developed over time and with exposure to clinical situation and so this may take time to achieve however The WCHN is on the correct path in the view of the ERT.

5.4.2.3 *Monitoring*

- Annual credentialling and review of CI competencies.
- KPIs are in place for
  - The review of the optimisation of the maps of new Paediatric CI patients with the Queensland Children's Hospital – targets have been identified and it is assumed that these will be reported as part of a suite of indicators.
  - The continued review of children, who are in the maintenance phase of their care, by the manufacturers.

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[117] Completed matrix documents were provided to the ERT for two staff. These documents did not show progressive assessment dates and are dated as signed off at end of June 2023.

[118] 2-day training from Cochlear 13th and 14th July – at elbow training on site, 1-day training MED-EL August 2023

- Internal review of all appointment schedules to ensure that it complies with recommended best practice timeframes.
- Audit of case notes to ensure compliance with the mapping procedure.
- Targets have been identified and it is assumed that these will be reported as part of a suite of indicators.

5.4.2.4 Model of Care

The WCHN has recently provided the ERT with a draft model of care document. This document, whilst an excellent endeavour, does not adequately address the fundamentals components of a model of care. Given the significant intervention required, particularly in the early years, for a child with profound hearing loss and the providers that are part of the MDT and model of care that includes audiology, early intervention, HAus, speech therapy and ENT consultation. Care is provided across multiple settings depending on the child's access to services and the capacity / capability of the service provider. The model of care needs to be reviewed in line with this expectation. A recommendation has previously been made in the report with this in mind.

5.5 OPPORTUNITIES FOR CLINICAL GOVERNANCE IMPROVEMENT OR FURTHER CHANGE AT THE WCHN

As part of the terms of reference the ERT was asked to consider other opportunities for improvement. In considering this the ERT has taken a very broad approach to this request and included opportunities for change for the WCHN, the DHW and more broadly Paediatric Cochlear Implant Programs in general.

5.5.1 DEPARTMENT FOR HEALTH AND WELLBEING

Like other health systems in Australia, SA operates a devolved governance structure[119] with its own Board to oversee the safety and quality system, risk, and corporate culture. It is the model by which SA's hospitals and health services are run at an arm's length from SA Health. In effect the hospital board, together with the Executive team, has substantial autonomy over local operational matters.

For devolution to be effective, it is contingent on a hospital's competence and its ability to make informed decisions. This is because, while local decision making is seen as a good thing, it relies on the capability of the decision-makers and the information that they have available to them. Weak performance assessment, reporting and evaluation of systems can easily create a situation where no-one feels they are responsible for quality and safety[120]. Devolution can only work if there are meaningful measures of performance, including safety and quality performance. SA Health could and should do more to ensure that hospitals are monitoring and improving the quality of their care. There are processes in place, at all hospitals, to manage the overall the safety and quality systems[121] of a hospital. The emphasis on this all of hospital approach can come at the expense of small pockets or programs within the organisation which is either underperforming or poses an operational risk because of critical mass, workforce, or capability issues. Major hospital safety scandals have occurred where the problem was restricted to a single service area (maternity services at Djerriwarrh Health Services, surgery at Bundaberg Base Hospital, and paediatric cardiac surgery at Bristol)[122]. It is not unreasonable to say that the average performance of these hospitals failed to reflect the extent of patient harm in specific areas. The major inadequacies that have emerged from the detailed reviews of these failures of clinical governance, where poor clinical and emotional outcomes for consumers have been a feature, remain consistent: a closed culture (often not receptive to new ideas or routine review of practices), failure of management to respond to known problems, limited and ineffective quality systems, poor communication with consumers, poor management of, and a lack of learning from what occurred through complaints and inadequate mortality and morbidity review.

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[119] Devolved governance model commenced 1 July 2019.

[120] Targeting Zero, Report of the Review of Hospital Safety and Quality Assurance in Victoria, Duckett et al., 2016.

[121] Accreditation is an evaluation process that involves assessment by qualified external peer reviewers to assess a health service organisation's compliance with safety and quality standards.

[122] Targeting Zero, Report of the Review of Hospital Safety and Quality Assurance in Victoria, Duckett et al., 2016.

Many saw the concerns that arose at the WCHN as the responsibility of the hospital. They were certainly 'operational' matters, but failure to follow up in a robust way indicates that the present role of the department potentially overemphasises the 'devolved' side of the governance equation, at the expense of appropriate accountability. South Australia Health has oversight of the state-wide incident reporting system as it is 'managed' by Safety and Quality – SLS Program[123] should have been fully aware of the CI concerns as they were reported. To detect potential risks to patients, it is imperative that the Department have the requisite oversight and provides support to the hospital and responds in a timely manner. The department needs a system of oversight that allows it to be more aware of safety and quality issues and how each is being investigated. This may mean being more connected to each hospitals Safety and Quality Unit and being provided with detailed reports particularly after an incident occurs. The point is to identify the appropriate level of oversight while also allowing the hospital to be autonomous as it addresses and manages operationally.

Recommendations

45. Review the Department for Health and Wellbeing's interpretation of the 'devolved governance' model to ensure adequate oversight and explore how the Department for Health and Wellbeing works with Local Health Network Safety and Quality Units including:

- Reporting that regularly occurs (including key performance indicators)
- Reporting that occurs after a cluster event (including key performance indicators)
- Reporting after a serious incident (including key performance indicators)

46. Review South Australia Health's performance monitoring framework and determine with hospitals a set of Key Performance Indicators that increase the focus on quality domains of safety, effectiveness, appropriateness, and patient experience.

47. Department for Health and Wellbeing review the Lookback Review Policy Directive, as a matter of urgency, and ensure that cluster events / incidents are always escalated to the Quality and Safety Unit of the Local Health Network.

- The Local Health Network Safety and Quality Unit is responsible to escalate to the Safety and Quality Unit at the Department for Health and Wellbeing.
- Any downgrade of the severity of the incident is overseen by the Local Health Network Safety and Quality Unit.
- Any cluster incident or significant event to be tabled at the Significant Event Review Committee within 60 days of the incident.

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[123] The SLS Program sits within Clinical System Support and Improvement structure at the DHW.

5.5.2 BOARD GOVERNANCE AND APPOINTMENTS

Hospital boards have an important role in matters of safety and quality. Amongst its fiscal responsibilities a board can set priorities for safety and quality and has a role in holding the CEO and other staff accountable. The Minister for Health and Wellbeing is responsible for appointing a board for the hospital consisting of persons who collectively have, in the opinion of the Minister, knowledge, skills and experience necessary to enable the board to carry out its functions effectively[124]. If a board is appointed that does not possess a good understanding of health services and the contemporary safety and quality in health care, there is a heavy reliance on the information shared by the CEO that often do not know the right questions to ask.

Weaknesses in board governance have been present at several international and Australian hospitals with high-profile failures in health care including Bristol Royal Infirmary[125], and Mid Staffordshire NHS Foundation Trust in England[126] and King Edward Memorial Hospital in Western Australia[127].

Provision of orientation for new board members and ongoing education is a LHN responsibility under a devolved governance model. There were different views provided to the ERT about the current Board member orientation including that there was no centralised approach to board member development to assist and understand their clinical governance responsibilities, including how to be inquisitive when matters of safety are discussed, particularly around small programs. The ERT was told that that the current WCHN Board had a strategic risk planning day on 11 May 2023 where they had a focus on the risks associated with small services, that are reliant on small numbers of skilled health professionals. The WHCN Board has recently increased its focus on safety and quality and as such the Board Clinical Governance Committee has increased recently increased their meeting frequency to bi-monthly.

Recommendations

48. The Department for Health and Wellbeing develop a board orientation program that focuses on the breadth of each board director's obligations particular in relation to safety and quality.

49. The Women's and Children's Health Network Board perform a skills matrix review and develop an education strategy to address any gaps.

50. The Women's and Children's Health Network Board undertake a board culture review to ensure that the board can have robust and respectful discussions and maintain independence from the leadership team.

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[124] Health Care Act (South Australia), 2008.

[125] Learning from Bristol: the report of the public inquiry into children's heart surgery at the Bristol Royal Infirmary 1984 - 1995.

[126] Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry, Francis, R., February 2013.

[127] Inquiry into the King Edward Memorial Hospital Obstetrics and Gynaecological Services (Douglas et al 2001).

5.5.3 SINGLE COCHLEAR IMPLANT SERVICE

As indicated throughout this report small, specialised programs can have issues with capability and capacity including the development and upskilling of staff. In models that are dependent on 'at elbow' training for staff to acquire skills and where there are a limited number of audiologists available consideration should be given to how best to design the overall CI program in SA.

There are currently two public provider of CI services in SA that operate completely separately. There may be benefits in considering bringing these two programs together to form a singular service. This may:

- Create addition capability in the service – audiologists could be trained in both paediatrics and adults.
- Consolidate senior staff (Managers) to allow them to concentrate policy and procedure development.

Distractors from such a model would argue that this would not work because the paediatric surgical component of the service needs to occur at the WCHN. A review of how other programs operate enables a model to be conceptualised where a singular CI program exists however components of it are delivered at other sites.

Recommendation

51. The Department for Health and Wellbeing together with the Local Health Networks review the model for the Cochlear Implant Program against other jurisdictions and consider moving towards a single Cochlear Implant service for South Australia which would enable capacity building across the system.

5.5.4 NEWBORN HEARING SCREENING

In July 2009, the Council of Australian Governments agreed to a proposal that Universal Newborn Hearing Screening (UNHS) would be available in all states and territories by the end of 2010. It is widely acknowledged that delays in the identification and treatment of permanent childhood hearing impairment may profoundly affect quality of life in terms of language acquisition, social and emotional development, and education and employment prospects[128].

Currently, all Australian UNHS programs[129] are state-funded, and every state/territory has achieved or is in the process of achieving a uniform screening program. There is a well-defined referral pathway from hearing screening to hearing aid fitting, which is federally funded. There are no synchronous processes after infants are referred for hearing aid fitting. Each state has different subsequent referral pathways due to the wide variety and availability of intervention processes, which are often dependent on non-government supports.

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[128] National Framework for Neonatal Hearing Screening, 2013, p. 4.

[129] Refer Appendix 2 for the Aims and Objectives of Neonatal Hearing Screening.

5.5.4.1 Newborn hearing screening in SA

The neonatal / newborn screening program in SA is held under the auspices of the WCHN. It involves approximately 30 birthing hospitals across the state. The Australian Institute of Health and Welfare (AIHW) were the leading agency in the development of national performance indicators to underpin a national reporting system for neonatal hearing screening in Australia. AIHW's proposed performance indicators are based on the aims, standards, and objectives for neonatal screening.

The target population is for all neonates >34 weeks' gestation to be screened within 24 to 72 hours of birth. The aim is to complete screening by four weeks corrected age[130]. Corrected age considers the time between premature birth and the actual due date of a full-term pregnancy. Calculating corrected age provides a more accurate reflection of what the baby's developmental progress should be as the child reaches it estimated due date. Protocols should be in place to ensure that screening can occur up to six months of age for babies not screened within the target time frame[131].

The Universal Newborn Hearing Screening Program in SA has established KPI targets which align with those within the National Framework. These are outlined in the Table 3 below:

Table 3 Universal Neonatal Hearing Screening Program Key Performance Indicators

Target Area	***Key Performance Indicators***
Screening Rates	**>97% of eligible SA births completed hearing screening by 30 days (corrected gestational age)** **>97% of eligible SA births completed a hearing screen before discharge from hospital Total of 4 audiologists**
Referral rates	**>80% of infants pass their hospital hearing screening in both ears** **<2% of babies screened are referred for diagnostic audiology testing**

Whilst not within the remit of the review, it is documented[132] and was reported to the ERT that SA performs below the national average across each target area. In 2021, nationally 72.4% of children with bilateral 3FAHL of 40dB or greater, were fitted with HAs by six months of age[133]. In comparison, 33.3% of SA children were fitted with HAs by six months of age for the same period[134].

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[130] National Framework for Neonatal Hearing Screening, 2013 p. 10.

[131] National Framework for Neonatal Hearing Screening, 2013 p. 10.

[132] Newborn Hearing Screening (sahealth.sa.gov.au)

[133] Hearing Australia. Demographic details of young Australians age less than 26 years with a hearing loss, who have been fitted with a hearing aid or cochlear implant, 31 December 2022.

[134] Hearing Australia. Demographic details of young Australians age less than 26 years with a hearing loss, who have been fitted with a hearing aid or cochlear implant, 31 December 2022.

The challenges that SA have in meeting this target were described to the ERT and include:

- History of poor culture of screening at birthing hospitals. The auspicing service has little impact on how this can be improved.
- Data integrity risks - data are manually recorded and there are limitations in the system that coordinates these data.
- The cost and responsibility of replacing equipment in the newborn screening program.

The potential consequences to these challenges are:

- Concerns around the pathway to further investigation and treatment of children with hearing loss in SA
    - Potentially not having early access to Hearing Australia and delays in having HAs fitted.
    - Overall delays in access to sound and EI services.
    - Delays in consideration for CIs.

This is indicative of a service and individuals under stress.

Recommendation

52. The Department for Health and Wellbeing and the Women's and Children's Health Network review the Universal Newborn Hearing Screening Program to improve the effectiveness and alignment with the national Key Performance Indicators.

5.5.5 MINIMUM STANDARDS FOR MAPPING IN PAEDIATRICS

A consistent theme during the review was the absence of national standards or guidelines for the frequency of mapping CIs. There appears to be good evidence that there are best practise principles that outline the frequency of mapping in children post cochlear implantation however this regime seems to be open for interpretation and is not consistently applied across the country. There is a real opportunity for a national body to develop the minimum standards for the mapping of Paediatric CIs following cochlear implantation. If such standards were developed and implemented across all paediatric providers compliance rates could form a reportable performance measure.

Recommendation

53. The South Australian Department for Health and Wellbeing advocate for the development of a consensus statement on the minimum standard for the frequency of mapping of cochlear implants in children in the first 12 months post cochlear implantation. The development of the consensus statement could be led by Audiology Australia.

5.5.6 MINIMUM STANDARD OF EDUCATION

Currently in Australia there is no formal paediatric cochlear implantation education program available which leaves all services reliant on a train the trainer model. However, AudA have recently developed a voluntary paediatric audiology certification framework which "enables audiologists experienced in the delivery of paediatric audiology at an advanced level of skill to apply for certification as a Certified Advanced Paediatric Audiologist"[135]. In the coming months AudA has plans to develop a voluntary paediatric certification system to accredit the higher-level specific skills expected of audiologists who provide paediatric cochlear implant services[136]. This is a positive step in developing consistency in skill development and an assurance of external accreditation.

Recommendations

54. All paediatric audiologists at the Women's and Children's Health Network to work towards advanced paediatric certification with Audiology Australia within the next 12 months.

55. All Paediatric Cochlear Implant audiologists at the Women's and Children's Health Network seek accreditation in the specific Cochlear Implant certification within 12 months of its release.

56. Providers of paediatric hospital-based audiology services consider requiring their staff to obtain advanced paediatric certification with Audiology Australia and accreditation in the specific Cochlear Implant certification following its release by Audiology Australia.

5.5.7 REQUIREMENT TO BE MEMBER OF AN ACCREDITED PROFESSIONAL BODY

Audiology is not a registered health profession with the Ahpra. However, AudA, the recognised professional organisation for hospital employed audiologists, provide a robust system for its members to be accredited. Audiology Australia require its members to adhere to a set of standards and to show evidence that they have completed annual CPD to remain accredited. This is not unlike the requirements of each of the National Boards for regulated health practitioners. If audiologists are accredited members of AudA, it may offer some reassurance to employers that these audiologists have at least met a minimum standard set and demonstrated that they have completed annual CPD.

Recommendation

57. Providers of paediatric hospital-based audiology services consider requiring their staff to be accredited members of Audiology Australia.

5.5.8 CONSUMER ENGAGEMENT

Consumer participation in their own health care is a fundamental component enshrined in the NSQHS Standards. Paramount to this is listening to consumers, particularly when they have concerns about how care is provided the outcomes of that care. The under-mapping issues that occurred at the Paediatric CI Program at the WCHN are a timely reminder that parents know their children best and that any concerns that a parent brings to the attention

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[135] https://audiology.asn.au/Advocacy/Advanced_Paediatric_Certification_Framework.

[136] 20200623 Audiology Australia Submission – independent review of WCHN Cochlear Implant Program.

of the treating team should not be ignored or played time. These events should have wider implications for providers of paediatric services and put all providers on notice and give each of them the opportunity to revisit how they engage and listen to parents and what systems each of them has in place to facilitate this engagement.

Recommendation

58. The Women’s and Children’s Health Network ensure that all their clinical services have processes in place that address parents'/consumer concerns. Parents/ consumers are provided written communication about these processes.

6. The way forward

The ERT would like to commend the Paediatric CI team at the WCHN for their openness and transparency in working with the ERT throughout the review. The ERT recognise and acknowledge that this has not been easy and that although necessary, the process has significantly impacted on key staff at the WCHN connected with the Paediatric CI Program. The ERT kept this front of mind during all the staff consultations. The ERT would also like to acknowledge the impact on the children and families affected by the issues and sincerely thank families for coming forward to tell their stories. Many of the stories were confronting for the ERT to hear.

The ERT have no doubt that the staff within the Paediatric CI Program and the Executive team at the WCHN are fully committed to improving the services of the Paediatric CI Program so it can continue to provide high quality, comprehensive and safe care to children and families. The ERT acknowledge that implementing all the recommendations will not be straightforward and will take resources and commitment from the WCHN and the DHW. We believe the recommendations will ensure that families can have confidence that the care they receive at the WCHN in relation to CI and subsequent follow up will be safe and of high quality comparable to relevant benchmark centres. The ERT was provided with the opportunity to make observations about the audiology / CI system more broadly and has taken the opportunity to consider the recommendations that might be adopted across CI programs nationally.

The ERT would also like to acknowledge the enormous contribution of the parents and carers who come forward to talk with us during the review. It was challenging for many of them to talk openly about sometimes years of frustration and the despair that they feel for the potential that some of their children have now lost. But this is not what has driven them to contribute to this review. Indeed, their desire to participate is to improve the system and processes for other families and other children to ensure that this does not happen again. It is in this vein that it is incumbent on the Minister for Health and Wellbeing, the DHW and the WCHN to ensure that the recommendations that are adopted are monitored and reported on regularly to the Board at WCHN and to the DHW.

Recommendation

59. Department for Health and Wellbeing work together with the Women's and Children's Health Network and convene a committee to oversee the implementation of the recommendations adopted from this report.

- Noting that a small number have wider implications and may not be relevant for the Paediatric Cochlear Implant Program
- The committee comprises representatives from
  - Paediatric Cochlear Implant team
  - Consumers who are part of the cochlear implant community – parents / carers / previous patients
  - Department for Health and Wellbeing
- Progress reports are provided in 3 monthly intervals

- Resources are committed to ensure the implementation of the recommendations adopted following this review.

7. Appendices

7.1 APPENDIX 1: TOTAL NUMBER OF CHILDREN

Number of Children	*Explanation*
208 Children	**Total number who had mapping undertaken at WCHN between 1 Jan 2006 - 31 Dec 2022** **- 196 children had their CI at WCHN** **- 12 children implanted elsewhere but have received mapping at WCGN**
196 children implanted at WCHN	**n = 146 who are <18 years** **n = 50 who are > 18 years** WCHN decided early to not include children in the lookback review who were over 18 years of age at the time the desktop review commenced
158 children included in lookback review	n = 146 implanted at WCHN n = 12 implanted elsewhere
Children contacted by the ERT	139 patients / families either made contact directly with the ERT through the public consultation or were contacted by registered mail (addresses supplied by WCHN) and invited to contribute. - of the letters sent in the registered mail four were returned to sender. 69 families that were part of the Paediatric CI program from 2006 were not contacted by the ERT. This was due to either lack of contact details or a specific request from the family to have no further follow up

7.2 APPENDIX 2: AIMS AND OBJECTIVES OF NEONATAL HEARING SCREENING

The aim of neonatal hearing screening[137] is for all babies to be screened for PCHI, and, if necessary, to have access to appropriate intervention to minimise the impact of their hearing impairment. Consistent with the Early Hearing Detection and Intervention guidelines[138], in Australia, the aim is to have infants screened by one month, hearing loss diagnosed by three months and intervention commenced by six months. This will improve the quality of life for children with PCHI in terms of their communication and language skills, subsequent education and employment prospects, and psychological wellbeing.

The objectives of neonatal hearing screening are to:

- Maximise the **early detection** of PCHI in Australian babies through the use of an approved screening test, and ensure appropriate follow up medical, and support services
- Ensure that all Australian families are offered the **opportunity** to participate in neonatal hearing screening
- Ensure **equitable** access to neonatal hearing screening for all Australian babies, irrespective of their geographic, socioeconomic, or cultural background
- Ensure that assessment services provided to babies requiring follow up care and intervention as a result of screening are **timely, acceptable, and appropriate** and are undertaken in accordance with professional standards
- Ensure families with babies diagnosed with impaired hearing are **referred** and have the **opportunity** to engage with an early intervention service following diagnosis
- Maximise benefit and minimise harm to the individual
- Achieve consistent standards of screening management, co-ordination, quality and safety, service delivery, monitoring and evaluation and accountability and ensure that the national approach to neonatal hearing screening is implemented in a manner that is cost effective and will significantly increase quality of life for Australian children with PCHI.

The National Framework focuses on having standardised screening pathway guidance across Australia, supported by evidence-based standards of practice. It is supported by a national approach to data collection, management, and data sharing through a national data set. The National Framework is a joint initiative between the Australian and state and territory governments in collaboration and partnership with specialists in the field of paediatric hearing and in consultation with families of children with hearing loss.

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[137] National Framework for Neonatal Hearing Screening, 2013, p. 8.

[138] Joint Committee on Infant Hearing. Year 2007 position statement: Principles and guidelines for early hearing detection and intervention programs. Pediatrics. 2007;120(4):898-921

7.3 APPENDIX 3: WOMEN'S AND CHILDREN'S COMMUNICATION TIMELINE

Date Sent	***Purpose of the Letter***	***To Whom***
16/9/22	Initial letter sent to Phase 1 families to advise them that the WCHN were aware of the issue	Phase 1 Families (117)
19/10/22	Sent to families "of concern" identifying next steps - require prioritised appointment	Phase 1 families (117) – those potentially "of concern
19/10/22	Sent to families "not of concern" identifying what they can do next - attend at scheduled appointment	Phase 1 families (117) – those considered "not of concern"
27/3/23	Information letter sent to Phase 2 families (under 18 y.o.)	Phase 2 families (41)
30/3/23	Progress letter to keep informed of the process	All families in Phase 1&2 (158)
26/5/23	**Email** correspondence sent from Manager, Audiology, to private providers advising of the standard information we will provide upon transfer to private provider (with consent of the family)	Paediatric Service Providers
29/5/23	Most recent letter sent to all families (Phase 1 & 2) to keep them informed of the process + information of alternative service providers	All families in Phase 1&2
29/5/23	Cover letter and same letter as above sent to all paediatric service providers	Paediatric service providers